**Washington State Prescription Drug Program**

# Interagency Report on the Implementation of Senate Bill 6088

**(Ch. 29 Laws of 2003, 1st Special Session)**

Pete Cutler, Acting Administrator, **Health Care Authority**
Dennis Braddock, Secretary, **Department of Social & Health Services**
Paul Trause, Director, **Department of Labor & Industries**

**January 2005**

# Acknowledgments


## Interagency Workgroup Members

*Washington State Health Care Authority*

**Duane Thurman**
Senior Prescription Drug Program Manager

**Erika Clayton**
Prescription Drug Program Coordinator

**Donna L. Marshall, PharmD**
Pharmacy Director, Uniform Medical Plan

**Mali Main**
Prescription Drug Program Assistant

**Jeff Graham, M.D.**
Prescription Drug Program Consultant

*Washington State Department of Labor and Industries*

**Thomas Davis**
Senior Health Policy Analyst

**Jaymie Mai, PharmD**
Pharmacy Consultant

**Roy Plaeger-Brockway**
Program Manager, Health Service Analysis

**Kristi Coulter, RPh**
Pharmacy Consultant

**Jim King**
Manager, Healthcare Policy and Payment Methods

*Washington State Department of Social and Health Services*
*Medical Assistance Administration*

**Doug Porter**
Assistant Secretary

**Siri Childs, PharmD**
Pharmacy Policy Manager

**Jeff Thompson, MD**
Medical Director

**Nicole Nguyen, PharmD**
Clinical Pharmacist, Pharmacy Program

**Roger Gantz**
Director, Division of Policy and Analysis

*Washington State Department of Social and Health Services*
*Aging and Disabilities Services Administration*

**Penny Black**
Director, Home and Community Services

**Susan Engles**
AAA Specialist

**Dan Murphy**
Chief of State Unit on Aging

# Table of Contents


**I. Introduction** ..... 1

**II. Executive Summary** ..... 1

**III. Progress Report on Implementation of SB 6088** ..... 3

Senate Bill 6088 section 2:
*Medicaid Prescription Drug Assistance Program (MPDA)* ..... 3

Senate Bill 6088 sections 3, 4, 11, and 12:
*Senior Prescription Drug Discount Program* ..... 4

Senate Bill 6088 section 7:
*Pharmacy Connection Program* ..... 6

Senate Bill 6088 section 8:
*Senior Drug Education Program* ..... 7

Senate Bill 6088 sections 5, 6, and 9:
*Evidence-Based Prescription Drug Program* ..... 9

**Appendix I. – Department of Social and Health Services letter to Legislature regarding Medicaid Waiver Status** ..... 20 – 27

**Appendix II. – Senior Drug Education Program/Pharmacy Connections Data** ..... 28 – 30

Senior Drug Education Program ..... 28

Connections Data Report ..... 29

Statewide Health Insurance Benefit Advisor (SHIBA) Report ..... 30
(Dec 2003 – Sep 2004)

**Appendix III. – Prescription Drug Program Background Documents and Data** ..... 31 – 59

Summary Overview of the Evidence-Based Review Process ..... 31

Preferred Drug Cost Analysis and Selection Process ..... 32

Agency Staff Analysis and Recommendation (Example) ……..…… 41

Exhibit 1: *Percent of Prescriptions on Preferred PDL Drugs Dispensed* ……..... 43

Exhibit 2: *Percent of Prescriptions on Preferred Drug List signed Dispense as Written* ……... 47

Exhibit 3: *Percent of Prescriptions on Preferred Drug List Prescribed by Endorsing Practitioner* …….. 51

Washington State Preferred Drug List …….. 55

**Appendix IV. – Pharmacy & Therapeutics Committee Information** ……... 60 – 76

Pharmacy & Therapeutics Committee Membership ……. 59 – 60

Pharmacy & Therapeutics Committee Plan of Operations ……..... 61 – 76

**Appendix V. – Laws and Rules For the Prescription Drug Program** ……..…… 76 – 86

Text of Senate Bill 6088 ……...…… 76 – 82
(Chapter 29 Laws of 2003, 1st Special Session)

Text of WAC 182-50 ……...……. 83 - 86

To obtain this publication in alternative format, please contact the Health Care Authorities Prescription Drug Program Coordinator at P.O. Box 91132, Seattle, Washington 98111-9232, 206.521.2027.

# I. Introduction

In June 2003, the legislature created the Prescription Drug Program (PDP) in Senate Bill 6088 (SB 6088) (Ch. 29 Laws of 2003 1st Special Session) to control state prescription drug costs without reducing the quality of care, to develop programs that provide affordable prescription drugs to those in need, and to increase public awareness regarding their safe and cost-effective use.

The PDP is a joint effort by the Health Care Authority (HCA), the Department of Social & Health Services (DSHS), and the Department of Labor & Industries (L&I) (hereinafter "the agencies"). It consists of five main components: a Medicaid Prescription Drug Assistance Program, a Senior Prescription Drug Discount Card, a "Pharmacy Connections" program, a Senior Drug Education Program, and an Evidence-Based Preferred Drug List (PDL)/Therapeutic Interchange Program (TIP).

The HCA has developed a comprehensive website (www.rx.wa.gov) where consumers, providers, and other interested parties can get comprehensive information about all of the state's prescription drug programs, as well as links to resources nationwide.

This progress report on the agencies' implementation of SB 6088 is submitted under the requirements of SB 6088 section 11.[1]

# II. Executive Summary

## SB 6088 section 2: Medicaid Prescription Drug Assistance Program (MPDA)[2]

DSHS did not apply to the Center for Medicare and Medicaid Services (CMS) to obtain a Pharmacy Plus waiver based on the federal government's enactment of the "Medicare Prescription Drug, Improvements and Modernization Act of 2003" (MMA). Beginning January 1, 2006, Medicare will begin offering prescription drug benefits (Part D) to Medicare beneficiaries. MMA also will provide low-income subsidies for beneficiaries with incomes up to 150% of the federal income guideline. Under MMA, Medicaid funding can no longer be used to finance prescription drug coverage for Medicare beneficiaries that would otherwise be covered under Part D.

## SB 6088 sections 3 and 4: the Senior Prescription Drug Discount Card[3]

The Senior Prescription Drug Discount Card became available June 1, 2004. It is a mail order discount drug program for Washington residents over 50 years old who have no other prescription drug coverage and who earn less than 300% of the federal income guideline (approximately $2,328 per month for an individual). The discount card costs

[1] RCW 41.05.530
[2] RCW 74.09.650
[3] RCW 41.05.500, 510; RCW 43.131.403

$10 per year and gives members a 15% to 25% discount on their prescription drugs. As of December 2004 approximately 25 residents have signed up for the discount card.

## SB 6088 section 7: the Pharmacy Connections Program[4]

The Pharmacy Connections program (1-888-435-3377) was established in December 2003, to provide toll-free telephone assistance for Washington residents to get information about manufacturer-sponsored prescription drug assistance programs and to assist them with applying for these programs. The program also serves as a one-stop "clearinghouse" to provide information on other prescription drug resources such as the Medicare discount cards and the Washington Senior Prescription Drug Discount Card. Since implementation, the program has provided assistance to over 15,000 Washington residents.

## SB 6088 section 8: the Senior Drug Education Program[5]

DSHS Aging & Disability Services Administration (ADSA) implemented the Senior Drug Education Program in November 2003. The program is designed to inform and train persons 65 and older in the safe and appropriate use of prescription and nonprescription medications. ADSA has provided grants to 11 Area Agencies on Aging to establish local programs. Programs range from distributing educational materials at health fairs, to individual classes that allow for one-on-one assistance to address specific medication regimens and their effects on each individual's health and lifestyle.

Over 7,100 seniors have received training or information as of November 2004, and future training will incorporate information about the Medicare prescription drug benefit and other options available.

## SB 6088 section 9: the Evidence-Based Preferred Drug List[6]

The Evidence-Based Preferred Drug List is a coordinated effort by HCA's Uniform Medical Plan (UMP), DSHS's Medical Assistance Administration (MAA) fee for service program, and L&I's Workers' Compensation Program to develop a statewide evidence-based PDL to encourage the use of less expensive, equally safe and effective drugs in state programs.

In January 2004, the agencies implemented a single PDL used by each of the agencies. As of January 1, 2005 the PDL consists of 12 drug classes. The agencies plan to add an additional 8 drug classes during 2005, and another 4 during 2006. The PDL will consist of 24 drug classes by January 2007.

The agencies select drugs for inclusion on the PDL based on the recommendations of the Washington State Pharmacy & Therapeutics Committee (P&T Committee). The P&T

[4] RCW 41.05.520
[5] RCW 74.09.660
[6] RCW 70.14.050

Committee was established on July 15, 2003 and meets at least quarterly to consider reports on the evidence of drug safety and efficacy produced by the Evidence-Based Practice Center at Oregon Health & Sciences University.

The P&T Committee makes recommendations to the agencies as to which drugs within a therapeutic class it believes needs to be included on the PDL and which are similar in safety and efficacy. The agencies then select a preferred drug, or drugs, from those drugs based on an analysis of net cost to the state.

To encourage the use of preferred drugs, SB 6088 sections 5 and 6[7] created a process by which practitioners can "endorse" the PDL. An "endorsing practitioner" is one who has reviewed the PDL and has notified the HCA that pharmacists can automatically "interchange" the preferred drug for any non-preferred drug prescribed unless the endorsing practitioner indicates, "dispense as written," or it is for a "refill" of certain drugs specified in the statute. In these situations a pharmacist will dispense the non-preferred drug as prescribed. The agencies implemented the practitioner endorsement and therapeutic interchange program (TIP) the week of May 1, 2004.

# III. Progress Report on Implementation of SB 6088

## SB 6088 section 2: Medicaid Prescription Drug Assistance Program (MPDA)[8]

**Legislative Summary:**

- Subject to specific appropriations and conditions, MAA shall design a Medicaid prescription drug assistance program that shall not be an entitlement program.

- MAA shall request federal waivers necessary to implement the program and may charge enrollment fees, premiums, or point-of-service cost-sharing. The benefit design shall be cost-effective and may differ from the medical assistance program benefit design. MAA may offer more than one benefit design and may include a deductible benefit to provide coverage when enrollees incur higher prescription drug costs.

- Eligibility is limited to persons who: are eligible for Medicare or age 65 or older; whose family income does not exceed 200% of the FPL; lack prescription drug insurance coverage; and are not otherwise eligible under Title XIX.

- Enrollment may be limited to prevent over expenditure or to comply with federal waiver budget neutrality requirements.

[7] RCW 69.41.150, .190
[8] RCW 74.09.650

- MAA shall recommend financing options to the legislature by November 15, 2003, including exploring opportunities to maximize federal funding. MAA may not reduce existing programs to comply with federal waiver requirements nor use premiums paid by non-program enrollees to finance the program.

- The program terminates within 12 months after implementation of a prescription drug benefit under Title XVIII.

**Implementation Status:** DSHS did not apply to CMS to obtain a Pharmacy Plus waiver based on the federal government's enactment of the "Medicare Prescription Drug, Improvements and Modernization Act of 2003" (MMA). Beginning January 1, 2006, Medicare will begin offering prescription drug benefits (Part D) to Medicare beneficiaries. MMA also will provide low-income subsidies for beneficiaries with incomes up to 150% of federal income guideline. Under MMA, Medicaid funding can no longer be used to finance prescription drug coverage for Medicare beneficiaries that would otherwise be covered under Part D.

In December 2003, DSHS submitted a letter and status report to Governor Locke and the chairs and vice-chairs of the health policy and appropriation's committees recommending that Washington not proceed with seeking a Pharmacy Plus waiver because it would only provide coverage for about 18 months before the new Medicare benefit became available **(See Appendix I. – DSHS letter to Legislature regarding Medicaid Waiver Status)** DSHS indicated that it would not be able to meet 5-year waiver budget neutrality requirements because most persons that might seek Pharmacy Plus coverage would be able to get subsidized covered under Medicare Part D.

With potential enactment of Part D, CMS informally told the states that it would no longer accept Pharmacy Plus waiver applications because of the impending enactment of Medicare drug coverage. At that time, CMS had granted waivers to only 4 of 16 states prior to the announcement of its moratorium on further applications, five other states had either withdrawn or rejected applications and the other applicants were on hold until Congress completed its deliberations on Medicare prescription drug coverage. DSHS was not appropriated funding to finance a Pharmacy Plus waiver and was advised by legislators not to take further action until after Congressional action on prescription drug coverage.

## Senate Bill 6088 sections 3, 4, 11, and 12: the Senior Prescription Drug Discount Program[9]

**Legislative Summary:**

- The HCA shall negotiate price discounts with prescription drug manufacturers for any Washington resident whose family income does not exceed 300% of the FPL; does not have prescription drug insurance coverage; and is 50 years or older; or

[9] RCW 41.05.500, 510; RCW 43.131.403

between 19 and 49 and eligible for federal old age, survivors, and /or disability insurance benefits.

- An individual's attestation is sufficient to satisfy the income eligibility requirement. However, any person who willfully makes a false statement to qualify for the discounts is guilty of a misdemeanor.

- HCA shall charge program participants an annual enrollment fee to offset program administration costs. All such fees are to be deposited into the consolidated prescription drug purchasing account.

- Pharmaceutical manufacturer rebates and discounts for individuals shall not be provided at the expense of retail pharmacies. This does not prohibit state agency discounted reimbursements for pharmacy services or ingredients.

- The program terminates as of June 30, 2010 and the section is repealed as of June 30, 2011.

**Implementation Status:** The Senior Prescription Drug Discount Card became available June 1, 2004. The discount card costs $10 per year and gives members a 15% to 25% discount on their prescription drugs.

The Senior Prescription Drug Discount Card is a mail order only program that is open to Washington residents covered by SB 6088 section 3 (residents over 50 or disabled who have no other prescription drug coverage, and who earn less than 300% of the federal poverty level) but that is specifically targeted at those who aren't eligible for the new Medicare discount card. The program is administered by Express Scripts, Inc. (ESI) under the HCA's Uniform Medical Plan (UMP) pharmacy benefits management contract. Administration costs for the discount card are supported by the $10 annual enrollment fee. ESI collects the fee, provides enrollment and renewal materials, determines eligibility, and provides customer support.

As of December 2004 enrollment in the discount program was approximately 25 members. The limited nature of the program is the result of several factors: (1) the availability of the Medicare drug discount card, (2) HCA's inability to negotiate discounts that did not come at the expense of retail pharmacies (not allowed by SB 6088), (3) the existence of many new discount programs offered by drug manufacturers, and (4) the fact that it is a mail order only program (most suitable for long term prescription drug needs).

- *Background on efforts to obtain individual discounts as envisioned by SB 6088.*

The UMP negotiates discounts from pharmaceutical manufacturers through its pharmacy benefits manager, ESI. Manufacturers were not inclined to extend these discounts to non-UMP members because without the underlying UMP benefit structure (3-tier co-

insurance), there is no incentive for purchasers to shift to a particular manufacturer's products, justifying a discount.

The HCA also explored the possibility of obtaining manufacturer discounts by using the Washington State Preferred Drug List to create incentives to shift market share to particular manufacturers' products. However, this program was not yet fully operational at the time of our negotiations and manufacturers wanted to see how the program actually worked before committing to any discounts based on it. Finally, manufacturers were focused on implementing the new Medicare prescription drug discount cards that became available June 1, 2004.

As a result the HCA met with the Chairs of the Senate Health and Long Term Care and House Health Care committees, and stakeholders to reach a compromise to provide a mail order only Senior Prescription Drug Discount Card to provide discounts to Washington residents covered by SB 6088 section 3, specifically targeting those who are not eligible for the Medicare discount card program.

## Senate Bill 6088 section 7: the Pharmacy Connection Program[10]

**Legislative Summary:**

- HCA shall establish a program to provide health care providers and the public, access to information about free or discounted medications from manufacturer-sponsored prescription drug assistance programs. The program specifically targets senior citizens, but is available to anyone. The program shall include a toll-free telephone number, available during regular business hours.

- Program staff help people gain access to these programs by:

    - Determining whether an assistance program is offered for a needed drug.
    - Evaluating the likelihood of a person obtaining drugs from an assistance program.
    - Assisting persons with the application and enrollment in an assistance program.
    - Coordinating with prescribers on communications on behalf of a person seeking access to an assistance program.
    - Working with manufacturers to simplify access to drug assistance programs, and to develop a single application form and uniform enrollment process.

- HCA may apply for and accept grants or gifts and may enter into interagency agreements or contracts with other state agencies to implement this program.

[10] RCW 41.05.520

- HCA shall notify pharmaceutical companies doing business in Washington of the program and the companies shall notify HCA of all relevant information regarding pharmaceutical assistance programs operated by the company.

**Implementation Status:** The Pharmacy Connections program (1-888-435-3377) was established in December 2003, to provide toll-free telephone assistance for Washington residents to get information about manufacturer-sponsored prescription drug assistance programs and to assist them with applying for these programs. The program also serves as a one-stop "clearinghouse" to provide information on other prescription drug resources such as the Medicare discount cards and the Washington Senior Prescription Drug Discount card.

The Pharmacy Connections program is administered through an interagency agreement between the HCA and DSHS, Aging & Disabilities Services Administration (ADSA). It is a coordinated effort involving 11 Area Agencies on Aging (AAAs); the Office of the Insurance Commissioner's Statewide Health Insurance Benefits Advisors (SHIBA), Senior Services of King County, and the Pharmaceutical Research and Manufacturer's Association (PhRMA).

The program also makes available a database of discount programs called "BenefitsCheckUp," which is a project of the National Council on Aging. Over 78 agencies in Washington State now use the database, and more than 300 agency staff and volunteers have been trained to use it as part of the Pharmacy Connections program. Since program implementation, AAA staff has provided referral information on drug manufacturer sponsored patient assistance programs and drug discount cards to over 15,000 individuals statewide. In addition to those contacts, they have also assisted over 11,000 individuals needing more help to complete applications. Included in the 11,000 are more than 5,300 BenefitsCheckUp screenings. SHIBA is also a partner in Pharmacy Connections, fielding more than 15,500 calls, over 11,000 web hits and making 627 public presentations. They also distributed over 70,000 pamphlets and flyers on related topics. **(See Appendix II. – Senior Drug Education Program/Pharmacy Connections Data)**

The number of contacts is expected to rise dramatically over the next six to nine months based on the confusion surrounding implementation of the new Medicare prescription drug benefit in 2006. All manufacturers offering discounts or free drug programs in Washington participate in Pharmacy Connections.

## Senate Bill 6088 section 8: the Senior Drug Education Program[11]

**Legislative Summary:**

- Each of the state's AAAs shall implement a program intended to inform and train persons age 65 and over in the safe and appropriate use of prescription and

[11] RCW 74.09.660

nonprescription medications. DSHS shall award development grants of up to $25,000 to each agency upon a showing that:

- The agency has the ability to administer a program;
- The agency can bring resources to the program in addition to those funded by the grant; and
- The program will be collaborative between the agency and health care programs and providers in the area served.

**Implementation Status:** DSHS Aging & Disability Services Administration (ADSA) implemented the Senior Drug Education Program in November 2003. The program is designed to inform and train persons 65 and older in the safe and appropriate use of prescription and nonprescription medications. ADSA has provided grants to 11 Area Agencies on Aging to establish local programs. Programs range from classes of 2-15 individuals to allow for one-on-one assistance to address specific medication regimens and their effects on each individual's health and lifestyle, to distribution of educational materials at health fairs. ADSA has developed the infrastructure necessary to make this program available throughout the state.

The additional funding allowed the AAA's to plan programs unique to their service area and population. Strategies included:

- Recruiting volunteer pharmacy professionals from the community to work one-on-one with seniors who would bring their medications to a "brown bag event."
- Training AAA staff to present appropriate materials at Senior Centers, senior housing, and other target locations.
- Staffing booths and disseminating materials (including Smart Cards for recording Rx info) at Health Fairs and other senior events.
- Developing and collecting educational materials through various resources.
- Training medical professionals to be more aware of geriatric standards for prescribing medications.
- Public Service Announcement media publicity of local phone number to call for information.

As of November 2004, more than 7,100 seniors have been trained or received information at 275 events utilizing 222 volunteers and staff. Future training will incorporate information about the Medicare prescription drug benefit and other options available. **(See Appendix II. – Senior Drug Education Program/Pharmacy Connections Data)**

## Senate Bill 6088 sections 5, 6, and 9: Evidence-Based Prescription Drug Program[12]

**Legislative Summary:**

Agencies administering state purchased health care programs shall cooperatively take actions to control costs without reducing the quality of care when purchasing drugs, including the development of the following:

- A "**Preferred Drug List (PDL)**" to limit the price paid for drugs through negotiated pharmaceutical manufacturer discounts.

- A "**Practitioner Endorsement**" process along with administrative rules necessary to govern the use of any list developed as part of the program.

- A "**Pharmacy and Therapeutics (P&T) Committee** to evaluate the effectiveness of prescription drugs in the development of the PDL.

- A "**Therapeutic Interchange Program**" to allow pharmacists filling a prescription for a state purchased health care program to substitute, where identified, a preferred drug for any nonpreferred drug in a given therapeutic class,

    - unless the endorsing practitioner has indicated the prescription be "**Dispensed as Written (DAW)**"

    - or the prescription is for a "**refill**" of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug.

- The pharmacist shall notify the prescribing practitioner of the specific drug and dose dispensed.
- A pharmacist who makes a therapeutic substitution assumes no greater liability for substituting the preferred drug than would be incurred in filling a prescription for the preferred drug when prescribed by name.

**Implementation Status:**

Preferred Drug List (See Appendix III. – Prescription Drug Program Background Documents and Data)

On February 12, 2003, the HCA adopted administrative rules creating a single statewide PDL and governing its use.[13] In January 2004, the agencies implemented the PDL. As of January 1, 2005 the PDL consists of 12 drug classes. The agencies plan to add an

[12] RCW 70.14.050; RCW 69.41.150, 190
[13] WAC 182-50-005 (7)

additional 8 drug classes during 2005, and another 4 during 2006. The PDL will consist of 24 drug classes of drugs by January 2007.

The current 12 drug classes and their uses include:

1. ACE Inhibitors (heart disease/hypertension)
2. Beta Blockers (heart disease/hypertension)
3. Calcium Channel Blockers (heart disease/hypertension)
4. Estrogens (hormone replacement therapy)
5. Long Acting Opioids (chronic non-cancer pain)
6. Nonsteroidal Anti-inflammatory Drugs & COX II Inhibitors (acute/chronic pain or inflammation)
7. Oral Hypoglycemics (diabetes)
8. Proton Pump Inhibitors (gastric reflux, gastric & duodenal ulcers)
9. Skeletal Muscle Relaxers (muscle spasms)
10. Statins (cholesterol reduction)
11. Triptans (migraine)
12. Urinary Incontinence Drugs (urinary incontinence)

The next 12 drug classes scheduled for review by the P&T Committee include:

1. 2nd Generation Antidepressants (depression and or psychiatric indications)
2. Non-sedating Antihistamines (allergies)
3. Angiotensin II Receptor Antagonists (heart disease or hypertension)
4. Atypical Antipsychotic drugs (schizophrenia)
5. Inhaled Corticosteroids (asthma)
6. Drugs for the treatment of Attention Deficit/Hyperactive Disorder
7. Drugs for the treatment of Alzheimer Disease
8. Anti-platelet drugs (cardiovascular disease/stroke)
9. TZD (a class of oral medications to treat diabetes mellitus)
10. 5HT3 Antagonists (drugs for the treatment of severe nausea and vomiting)
11. Anti Tissue Necrosis Factor (treatment of diseases such as rheumatoid arthritis)
12. Sedative Hypnotics (sleep medication)

Endorsing Practitioner/Therapeutic Interchange Program (TIP)

*Endorsing Practitioners*: To encourage the use of preferred drugs, TIP allows practitioners to review and "endorse" the PDL and notify the HCA that pharmacists can automatically "interchange" the preferred drug for any non-preferred drug prescribed unless the practitioner indicates "dispense as written (DAW), or the prescription is for a "refill" of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drugs. In these situations the pharmacist will dispense the non-preferred drug as prescribed.

The agencies implemented TIP the week of May 1, 2004. There are approximately 5300 practitioners who have endorsed the PDL out of a total of approximately 27,000 licensed

practitioners who have prescriptive authority in the state, of which the agencies estimate 15,000 write the bulk of the prescriptions affected by this program.

*Administrative Rules and the "Refill" exemption:* on February 12, 2004, HCA adopted administrative rules to govern the TIP program. These are codified in WAC 182-50. While none of the specified drugs subject to the "refill" exemption are currently listed on the PDL, WAC 182-50-005 (9) defines "refill" to mean "the continuation of therapy with the same drug (including the renewal of a previous prescription or adjustments in dosage) when a prescription is for an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug. Thus, when these specific drugs come onto the PDL a patient will continue to receive these drugs when a prescription expires and must be renewed by the treating practitioner. TIP will only occur for the initiation of therapy for these drugs, although the DAW exemption to TIP for endorsing practitioners will still apply.

*Drugs not listed on the PDL:* drugs that are in classes that are not part of the statewide PDL remain subject to the individual agency's prior authorization requirements, brand limits, or generic substitution under previously existing law.

*Non-endorsing Practitioners:* non-endorsing practitioners continue to be subject to prior authorization as applicable, even when they sign DAW on prescriptions. In addition the MAA four brand limit still applies. Practitioners have an incentive to endorse the PDL because they will see a reduction in the need for prior authorization, rewriting prescriptions and the associated administrative costs.

*Endorsing Practitioner Database:* to support implementation of the practitioner endorsement program, HCA used its existing pharmacy benefits management contract with ESI to develop an endorsing practitioner database that allows practitioners to sign up as an endorsing prescriber and allows pharmacists to determine the endorsing status of a practitioner. In addition, ESI coordinates with HCA on outreach, customer support, and providing statistical data to the agencies. **(See Data Exhibits 1 – 3, Appendix III. – Prescription Drug Program Background Documents and Data)**

HCA entered into an interagency agreement with the Department of Health (DOH) which allows DOH to provide information on practitioners who have prescriptive authority in Washington State. ESI uses this information to maintain the endorsing practitioner database and match practitioners by program identification number for therapeutic interchange purposes. The agencies also use this data to communicate with practitioners in the state.

*Stakeholder Outreach Efforts:* to publicize the endorsing practitioner program, the agencies worked with the Washington State Medical Association (WSMA), the Washington State Pharmacy Association (WSPA), the National Association of Chain Drug Stores (NACDS), the Board of Pharmacy (BOP) and other stakeholders to develop outreach information and training materials. The agencies also held various general information sessions.

During March and April 2004, agency staff worked with Washington State Pharmacy Association (WSPA) to conduct 10 training sessions around the state. Since then, the agencies have posted information and training materials on the www.rx.wa.gov website and provided ad hoc training as required.

In addition, the agencies have contracted with ePocrates as of November 2004. eProcates is a software program for prescribers that contains drug information and formulary information for most major third-party insurers in Washington state. MAA has had its PDL information posted on ePocrates since December 2002. HCA and L&I plan to have their information posted by February 2005.

Finally, the agencies are developing a quarterly update mailing of changes to the PDL to keep practitioners aware of the drugs subject to therapeutic interchange and allow them to review their endorsing status.

The Pharmacy & Therapeutics (P&T) Committee *(See Appendix IV. – Pharmacy & Therapeutics Committee)*

The agencies selected the Washington Pharmacy & Therapeutics Committee (P&T Committee) members on July 15, 2003. The committee held its first meeting on September 24, 2003. The committee meets quarterly, (with additional meetings as necessary) to consider evidence-based reviews created by various Evidence-Based Practice Centers (EPCs) and make recommendations to the agencies as to what drugs to include on a state-wide preferred drug list (PDL) and subject to therapeutic interchange by the agencies.

As of January 2005, the P&T Committee has held 7 meetings and made recommendations on 12 drug classes. The committee is scheduled to meet 6 times in 2005 and review another 8 new drug classes and another 4 during 2006. By January 2007 the P&T Committee will have reviewed a total of 24 drug classes. The committee will continue to meet periodically to undertake updated reviews of existing drug classes on at least an annual basis, thereafter.

*P&T Committee Administrative Rules and Plan of Operations:* On February 12, 2004 the HCA adopted administrative rules to govern the P&T Committee's operations including member selection criteria, terms of service, ethics and conflict of interest standards. On December 17, 2003 the P&T Committee adopted a Plan of Operations. The Plan establishes member terms of service, governance, ethics, conflict of interest and scope of review policies. The agency directors approved the Plan on January 13, 2004

*P&T Committee Selection criteria:*[14] because the P&T Committee also fulfills the role of the Drug Utilization Review (DUR) Board required for MAA, it must also meet federal CMS requirements applying to state Medicaid programs, in addition to the requirements established by the agencies by rule.

[14] WAC 182-50-025

To meet CMS requirements, physicians and pharmacists must each represent between 31 and 51 percent of board membership. To address this requirement the agencies established a P&T Committee with 10 members that include 4 physicians, 4 pharmacists, and two ancillary healthcare providers.

CMS regulations also require that members serving on a DUR Board have recognized knowledge and expertise in one or more of the following:

- Clinically appropriate prescribing of covered outpatient drugs
- Clinically appropriate dispensing and monitoring of covered outpatient drugs
- Drug use review
- Medical quality assurance
- Disease state management

Finally, CMS regulations require that members be actively practicing in their clinical area of expertise.

Additional Criteria for State P&T Committee Selection: to address the goals of the legislation and best meet program needs, the agencies adopted the following selection criteria were added to the above federal criteria for determining P&T Committee membership:

- Candidate is not currently employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any agency administering state purchased health care programs
- Candidate's main practice focus is outpatient care
- Specialties represented on the Committee will include Family Practice, Internal Medicine, or Behavioral Health (due to the major role of these specialties in prescribing medications taken by program participants)
- Candidate has experience in evidence-based medicine
- Previous experience serving on a pharmacy and therapeutics committee
- Committee membership is representative of programs' geographic distribution
- Candidates who are active in professional societies are preferred
- Candidate has not had any state licensure actions or Medicaid/Medicare sanctions

*P&T Committee Selection Process:*

In April 2003, the agencies began to compile nominations for the P&T Committee. The request for nominations was formally announced at the Drug Utilization Education Council (DUEC) meeting in June 2003, and disseminated through the Washington State Medical Association (WSMA), Washington State Pharmacy Association (WSPA), and Washington State Academy of Physicians Assistants (WAPA). The agencies also took several nominations from groups or individuals who made inquiries.

In total, 11 physicians, 12 pharmacists, 2 physician's assistants and one ARNP were nominated. Each agency's pharmacy director and medical director reviewed the 25 nominees, based on the criteria shown above, to recommend candidates for the P&T Committee.

On July 15, 2003, the agency directors unanimously selected the final 10 members. The members will serve staggered 3-year terms. They include the targeted specialties and desired geographic distribution (four of the recommended candidates are from Eastern Washington). Collectively, they are active practitioners and represent a large number of provider training programs (such as physician residency programs) and professional associations. Four members previously served on the MAA DUEC Committee.

*P&T Committee Terms of Service/Vacancies*:[15]

- Members shall be appointed to a term of three years until a successor is duly appointed.

- A member may be re-appointed to one additional three year term for a total of six years. One year after the end of the six year term a person is eligible for appointment to an additional three year term.

- Committee members shall serve staggered three years terms. Of the initial appointees in order to provider for staggered terms, some members may be appointed initially for less than three years. If the initial appointment is for 24 or fewer months, that period of time shall not be counted toward the limitation of years of appointment described above.

- Vacancies on the committee will be filled for the balance of the unexpired term from nominee lists for the appropriate committee category as provided under WAC 182-50-025.

*P&T Committee Officers*: The P&T Committee Plan of Operations, section M. (1)-(9) provides that:

> 1) A Chair and a Vice Chair, selected by the members, shall manage the Committee and such other officers as are deemed necessary to administer the affairs of the Committee.
>
> 2) The term of office shall be for two years beginning on January 1st of the year following selection. Each officer shall hold office until a successor is duly elected.
>
> 3) The officers of the Committee shall fulfill the following functions:

[15] WAC 182-50-030; Plan of Operations Section I.

a) Chair: The chair shall be the principal executive officer of the Committee and shall generally supervise and control all of the business and affairs of the Committee. The Chair will be selected in even numbered years. The Chair may appoint such other officers, subcommittees, working groups or advisory groups, as he or she deems appropriate. The Chair shall:

i) Preside at all meetings of the Committee;

ii) Assist with the development and implementation of a program to publicize the existence of the Committee, qualifications for appointment and procedures for maintaining public awareness of the Committee;

iii) Complete an annual report of the activities of the Committee by May 1st of each year and forward it to the Appointing Authority; and

iv) Shall serve as an ex-officio member of all subcommittees, working groups or advisory groups.

b) Vice Chair: The Vice Chair shall perform all duties of the Chair in the absence of the Chair or when the Chair is unable to act or refuses to act. When so acting, the Vice Chair shall have all of the powers and be subject to all of the restrictions of the Chair. The Vice Chair will be selected in odd numbered years. In addition, the Vice Chair shall:

i) Perform such other duties as may be assigned by the chair or the Appointing Authority.

ii) Act as the designee of the chair as ex-officio member of all Committees, working groups or advisory groups of the Committee.

4) Any officer selected or appointed by the Committee may be removed by a majority vote of the full Committee whenever in its judgment the best interests of the Committee would be served thereby.

5) The Chair and the Vice Chair should not be employed by the same entity. The Committee should strive to select officers from different regions of the state whenever possible.

6) For the 2003-4 year, the Chair shall be selected for a two-year term and the Vice Chair selected for a one-year term.

7) In the absence of both the Chair and the Vice Chair, an acting vice chair shall be appointed by a majority of the Committee present at that meeting and shall preside at that meeting of the Committee.

8) If a vacancy occurs in the office of Chair due to his or her death, resignation, removal, disqualification or other act of the Committee or the Appointing Authority, the Vice Chair shall automatically fill such vacancy until a successor is elected at the next regularly prescribed time. If a vacancy occurs in the office of Vice Chair, he or she shall be replaced by a majority vote of the members for the remainder of the term.

9) If contested, all elections of officers shall be conducted by secret ballot.

*The P&T Committee Conflict of Interest Policies and Procedures:* WAC 182-50-025 (8)-(11) provides that:

8) Members of the committee shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any state agency administering state purchased health care programs during their term shall not have been so employed and for eighteen months prior to their appointment.

(9) A member shall not have a substantial financial conflict of interest including any interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant moneys. The appointing authority in its sole discretion may disqualify any potential member if it determines that a substantial conflict of interest exists.

(10) As part of the application process, prospective committee members shall complete a conflict of interest disclosure form, provided by the appointing authority, and after appointment, annually by July 1st of each year. Members must keep their disclosure statements current and provide updated information whenever circumstances change.

(11) Committee members must agree to keep all proprietary information confidential.

The P&T Committee's Plan of Operations also contains specific conflict of interest policies and procedures as set forth in section H. (6)-(10):

6) Members of the Committee shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any state

agency administering state purchased health care programs during their term and for eighteen months prior to their appointment.

7) No member may have a substantial financial conflict of interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant monies. Members shall update their Conflict of Interest disclosure statements any time their circumstances change in order to ensure their information is current.

8) Any person appointed as a member of the Committee or any subcommittee, working group or advisory group established by the Committee, must disclose to the Appointing Authority any potential conflict of interest, including receipt of any remuneration, grants, or other compensation from a pharmaceutical manufacturer or pharmaceutical benefits management company prior to such appointment.

9) At each meeting any member of the Committee must recuse himself or herself from discussion and decision making of an entire drug class if he or she has a material conflict with any drug in that class. If any material conflict of interest is not disclosed by a member of the Committee on his or her application or prior to participation in consideration of an effected drug class or other action of the Committee, that person shall be subject to immediate dismissal.

10) Committee members shall not use the name of the Committee in any publication, meeting, negotiation, or promotion without prior approval of the Appointing Authority.

*P&T Committee Evidence-Based Review Standards:* The Washington P&T Committee's review process is set forth in its Plan of Operations; section G. (1)-(7):

The P&T Committee will evaluate evidence-based reviews of classes of prescription drugs provided by OHSU EPC or other contracted entity. The evidence-based reviews shall be based on well designed, well-conducted studies that:

1) Consider the overall quality of the evidence available at the time of review, including a consideration of whether the study compares the safety, efficacy or effectiveness of similar drugs, rather than just compared to placebo;

2) Select and refine questions that assist the Committee in evaluating provider and patient perspectives;

3) Make use of an independent, systematic review of evidence of the relative safety, efficacy, and effectiveness of prescription drugs in a class;

4) Produce explicit, defensible recommendations based on careful evaluation of the available evidence at the time of the review;

5) Evaluate each class of drugs in a manner free of bias emphasizing the best evidence as reported by OHSU or other entity;

6) Review direct evidence, if available at the time of review, that addresses health outcomes rather than intermediate outcomes, including the spectrum of patients to whom a drug will be prescribed (not just highly selected patients in research studies); and

7) Consider the potential harms as well as the benefits of the intervention being considered.

The P&T Committee may consider such other evidence and reviews as the Committee deems appropriate to a well-informed review.

*The Evidence-Based Review Process (See Summary Overview, Appendix III. – Prescription Drug Program Background Documents and Data):* The agencies participate in the Drug Effectiveness Review Project (Project) to provide evidence-based reports prepared by various Evidence-Based Policy Centers (EPCs) for the P&T Committee to review. This Project is coordinated by the Center for Evidence-Based Policy at Oregon Health & Sciences University (OHSU). The Project is a collaboration of twelve states and two non-profit organizations to obtain the best available evidence on effectiveness and safety comparisons between drugs in the same therapeutic classes.

*The Role of the OHSU Center for Evidence-Based Policy:* The Center for Evidence-Based Policy supports the collaboration by executing the agreements and contracts required to operate the collaboration, and by staffing the governance process that directs the Project. In addition, the Center supports communication between the participating organizations and the EPCs, provides technical assistance to participating organizations, ensures that timelines are met, and manages communication among the participating organizations, and between pharmaceutical companies and the Project. The Center for Evidence-Based Policy does not participate in the evaluation of the evidence.

*The Role of the Evidence-Based Practice Centers (EPC):* The Project relies on a series of comprehensive, updated and unbiased systematic reviews conducted by the various EPCs, which are designated and funded by the Department of Health and Human Services, Agency for Healthcare Research and Quality.

The EPCs perform systematic reviews of medical evidence comparing the safety, efficacy, and effectiveness of these drug classes and updates these reviews at least every twelve months. As a part of the review process, the EPC consults with health care specialists and other stakeholders to provide feedback to ensure that the concerns of patients and practitioners are thoroughly considered, and develops key questions to guide the systematic reviews. The key questions specify the clinical conditions (diagnoses,

disease) of interest for the particular review; define the populations, interventions, and outcomes (expected benefits, potential risks or harms) of interest for the systematic review; and distinguish intermediate outcomes (e.g. laboratory test results or biometric measures) from true health outcomes (e.g. death, morbidity, functioning, quality of life) and focus the research on true health outcomes when possible.

The Role of the Oregon EPC is to provide support to the agencies and the P&T Committee as it reviews the evidence presented. The reports created by the Oregon EPC only consider the available scientific evidence without regard to drug cost information.

*The Role of the Washington State P&T Committee:* All P&T Committee meetings are open to the public and notice is published in the Washington State Register and sent to interested parties as required by state open public meetings law. The P&T Committee also notifies interested parties of its intent to consider a particular class of drugs for inclusion on the state's preferred drug list 30 days prior to meeting.

At each meeting the P&T Committee reviews the report created by the EPC on a particular drug class with assistance from EPC staff and considers stakeholder comments. The P&T Committee then evaluates the evidence of similar safety, efficacy, and effectiveness for the drugs in a class and makes a recommendation to the agencies as to which drugs (if any) in a given class are essentially the same in terms of safety and efficacy and thus can be subject to therapeutic interchange.

The P&T Committee has developed a schedule for evaluation of both the drug class reviews and annual updates developed by the EPC. See more at: www.rx.wa.gov

*The Role of the State Agencies:* The next step is for the agencies to review the P&T Committee's recommendations as to which drugs (if any) in a class can be safely interchanged and to perform a cost analysis of those drugs to determine which drug, or drugs should be on the PDL. The agencies' cost analysis process is set forth in **Appendix III. – Prescription Drug Program Background Documents and Data**, along with an example of the resulting recommendation summary that is produced for each drug class.

# Appendix I.

# Department of Social and Health Services letter to Legislature regarding Medicaid Waiver Status

STATE OF WASHINGTON

# DEPARTMENT OF SOCIAL AND HEALTH SERVICES

P.O. Box 45010, Olympia, Washington 98504-5010

December 31, 2003

The Honorable Helen Sommers
Chair, House Appropriations Committee
P.O. Box 40600
Olympia, Washington 98504-0600

Dear Representative Sommers:

This is to provide a status report on Chapter 29 Laws of 2003, E1, Section 2 (SB 6088) provisions that direct the Department of Social and Health Services (DSHS) to obtain a Medicaid Pharmacy Plus waiver. This waiver would allow the department to offer subsidized prescription drug coverage to low-income seniors and other low-income Medicare beneficiaries. DSHS also was directed to report to the Legislature on options to finance the waiver.

The recent enactment of the "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" (the Act) alters the need for a transitional Medicaid prescription drug benefit. The Act implements a new Medicare Part D prescription drug benefit coverage, which will provide prescription drug coverage to nearly all of the target population for this chapter law. It will provide low-income assistance to 70 percent of the target population. Under existing law, implementation of Part D coverage in January 2006 would trigger the termination of the Pharmacy Plus waiver within twelve months and make it unlikely that waiver budget neutrality requirements could be achieved. Based on available information, the federal Department of Health and Human Service's (HHS) Centers for Medicare and Medicaid Services (CMS) may withdraw the Pharmacy Plus waiver option. I am therefore recommending that we not proceed with obtaining a Pharmacy Plus waiver at this time.

## CHAPTER 29, LAWS OF 2003, E1 (SB 6088) REQUIREMENTS

The Governor's 2003 request drug legislation (HB 1214) included a provision to obtain a Pharmacy Plus waiver to assist low-income seniors to obtain affordable prescription drug coverage until Congress adopted Medicare prescription drug coverage.

Chapter 29, Laws of 2003, E1 (SB 6088) adopted the Governor's recommendation and directed DSHS to implement a Medicaid prescription drug assistance program. The Medicaid prescription drug assistance program was intended to provide subsidized prescription drug

coverage to persons over age 65 with incomes up to 200 percent of the federal poverty level (FPL) and to other Medicare beneficiaries with incomes up to 200 percent of FPL. The program was conditioned upon necessary state funding and obtaining a Medicaid Pharmacy Plus waiver.

As a demonstration waiver, the drug assistance program was not to be a Medicaid entitlement program. Enrollment would be limited to funds appropriated for the program. DSHS was given authority to adopt a benefit design that is different than the existing full-scope Medicaid prescription drug benefit that includes over-the-counter drugs and supplies. The department was also given authority to adopt enrollment fees for the program and copayment provisions that are beyond the scope of existing federal Medicaid limitations.

The 2003 legislature did not appropriate funds for the Medicaid prescription drug assistance program. Instead, Chapter 29, Laws of 2003, E1 (SB 6088) directed DSHS to obtain necessary federal Medicaid waivers to finance the program. It also directed the department to identify and recommend financing options to the Legislature by November 15, 2003. Chapter 29, Laws of 2003, E1 (SB 6088) prohibited savings from implementation of premiums for Medicaid optional children to be used to finance the program.

The prescription drug assistance program was intended to be a transitional coverage program. Chapter 29, Laws of 2003, E1 (SB 6088) directed the department to terminate the program within 12 months after Medicare prescription drug coverage was implemented.

## PHARMACY PLUS PROGRAM

In March 2002, CMS introduced a new 1115 demonstration waiver (called Pharmacy Plus) that allows states an opportunity to expand prescription drug coverage to certain low-income elderly and disabled individuals. The Pharmacy Plus waiver was part of the Bush Administration's strategy to help provide prescription drug coverage to seniors.

The waiver is limited to persons with incomes up to 200 percent of FPL. The waiver allows states to have a different prescription drug benefit design than is offered to regular Medicaid client, impose cost-sharing and enrollment fees, and to limit enrollment in the program to achieve required "budget neutrality."

Under the Pharmacy Plus demonstration, states are expected to expand Medicaid prescription drug coverage to low-income seniors (and disabled persons if part of the waiver coverage) and spend no more for Medicaid services to elderly persons enrolled in Medicaid (regular clients and

waiver clients) than the state would have spent for elderly clients in Medicaid absent the expanded pharmacy coverage.

Medicaid savings from the waiver are to be achieved by reducing the number of persons enrolling in the regular Medicaid program or reduce utilization of Medicaid acute, chronic and long-term care services for elderly persons. Budget neutrality must be achieved by the end of the 5-year demonstration period. This allows states to spend more federal and state funds for Medicaid coverage during the earlier years so long as savings are achieved by the end of the demonstration period.

To date, 16 states have submitted Pharmacy Plus waiver applications. Four states have approved waivers, 3 states have withdrawn their applications, 2 states have disapproved applications, and 7 states have pending applications.[1]

## MEDICARE PART D COVERAGE [2]

The President signed the "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" on December 8, 2003. The Act creates a new prescription drug benefit (Part D), Medicare program reforms, and certain Medicaid-related provisions.

Medicare Part D coverage will begin January 2006. Enrollment in Medicare Part D coverage is optional. Full-benefit Medicare/Medicaid dual eligibles who do not select a Part D plan will be automatically enrolled in a plan, but will have the option to decline enrollment or change plans.

There will be a 6-month initial enrollment period beginning on November 15, 2005 for all persons who are eligible for Part D on that date. Persons who become eligible after that date will have an initial enrollment period of not less than 6 months.

HHS will establish regions across the country where private insurers will bid to provide prescription-drug coverage to Medicare beneficiaries, either through a prescription drug-only

---

[1] A General Accounting Office (GAO) study of Medicaid waivers raised serious questions about several approved states' Pharmacy Plus waivers being budget neutral.

[2] State agencies, National Association of State Medicaid Directors (NASMD), National Governor's Association (NGA), National Council for State Legislators (NCLS) and other public and private organizations are still reviewing the "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" provisions. The overview in this letter is primarily from NASMD, NCLS, FamiliesUSA and Covington & Burling.

plan (PDP) or a comprehensive health plan. If no private plans bid to serve a region, then a HHS sponsored plan would provide coverage in that area.

PDP sponsors must offer coverage that is at least equal in value to a standard benefit, but some details may vary from plan to plan. The standard includes: a monthly premium of about $35, a yearly deductible of $250 and 75 percent coverage up to $2,250. There is no coverage for expenses between $2,250 and $5,100. Enrollees are responsible for paying entirely for $2,850 in expenditures (so called "gap" or "doughnut hole"). Above $5,100 the individual would then be responsible for either 5 percent co-insurance *or* co-pays; $2 for generic and preferred drugs and $5 for all other drugs, whichever is greater.

Each plan that offers Part D coverage will be permitted to implement a formulary, subject to certain requirements. A pharmaceutical and therapeutic (P&T) committee must develop and review the formulary. The formulary must include at least one drug within each therapeutic category or class of covered Part D drugs, based on a list of categories and classes developed by the U.S. Pharmacopoeia. The Act allows for the plans to exclude drugs for weight loss or gain, hair loss or excessive hair growth, and fertility, as well as over-the-counter drugs. However, smoking cessation drugs will be covered.

Medicaid federal financial participation (FFP) cannot be used to provide for drugs or cost-sharing for drugs for full-benefit eligibles (low-income persons with both Medicare coverage and Medicaid coverage that includes prescription drug coverage). There are seven classes of drugs that states can continue to offer to full benefit dual-eligible clients. A state choosing to offer other drugs offered by their Medicaid plan, which are not covered by Part D or the seven additional classes of drugs, can only do so at 100 percent of state expense.

The Act provides for low-income assistance for certain Medicare beneficiaries. For full-benefit dual eligibles with income up to 100 percent of the FPL, beneficiaries would pay no premiums, no deductibles, co-pays of $1 for generic and preferred drugs and $3 for all others. They also would be exempt from the coverage gap.

Beneficiaries who meet the asset test and earn below 135 percent of FPL ($12,123 for individuals, $16,352 for couples), would pay no premium and no deductible, with co-pays of $2 for preferred drugs, $5 for all others. They would be exempt from the coverage gap. The asset test allows for three times the current SSI standard ($6,000 for an individual / $9,000 for a couple). Reportedly, there is no cost-sharing for institutionalized individuals with incomes up to 135% of FPL.

A third group with individual incomes of no more than 150 percent of FPL ($13,470 for individuals and $18,180 for couples) would be allowed to have assets of no more than $10,000 individually, $20,000 per couple. They would pay some premium on a sliding scale up to $35, have a $50 deductible, coverage that paid 85 percent of costs up to the $3,600 limit and co-pays of $2 or $5 per prescription after that limit is reached. They also would be exempt from the coverage gap.

Under the Act, the Medicare program is to assume financial responsibility for Part D costs for full-benefit dual eligibles. However, states will be required to reimburse the federal government for a portion of states' share of the full-dual eligibles' drug costs. Under "phased-down state contribution requirements" (so-called "clawback formula"), states will be required to pay 90 percent of state cost in 2006, decreasing to 75 percent over ten years. States will be required to pay a per-capita amount for each full-benefit dual eligible that is enrolled in Part D coverage. The per-capita amount that states will have to repay will be increased each year, based on the national per-capita increase in Part D expenditures.

The clawback formula's cost implications for states are not yet known. States would have to only pay a percent of their state fund obligations. However, this savings could be offset by increases in Medicare per-capita drug costs that are greater than a state's drug costs for dual-eligibles. DSHS will be developing estimates for these costs over the next several months. State clawback payment obligations will begin in January 2006.

States and the Social Security Administration will both be required to administer eligibility programs for low-income assistance. DSHS will be facing an additional financial burden for conducting the eligibility reviews and enrollment activities related to the low-income assistance for Medicare beneficiaries. States will be able to treat these costs as Medicaid expenditures and receive regular administrative and IT FFP match rates.

Some states may also experience a 'woodwork effect' during the eligibility determination process. Applicants for the Medicare drug benefit may be deemed eligible for Medicaid. Between the clawback provision, the possible increase in Medicaid eligibles, and the additional administrative burden, some states may experience costs greater than they would have absent the Medicare prescription drug program, particularly in the first few years.

## PART D & PHARMACY PLUS COVERAGE RELATIONSHIP

As described above, the Chapter 29, Laws of 2003, E1 (SB 6088) Medicaid prescription drug assistance program is intended to provide transitional, subsidized prescription drug coverage to persons over age 65 with incomes up to 200 percent of FPL and to other Medicare beneficiaries with incomes up to 200 percent of FPL. Based on 2002 Washington State Population Survey (2002WSPS) data for April/May 2002, there were approximately 186,000 seniors and 27,000 Medicare beneficiaries under age 65 with incomes up to 200 percent of poverty. Up to 181,000 (97 percent) of these 213,000 persons would be eligible for Part D coverage. Some of the remaining 5,000 persons may not be eligible for Medicaid Pharmacy Plus due to their citizenship status.

The Part D low-income assistance is available to Medicare beneficiaries with incomes up to 150 percent of FPL. Based on the 2002 WSPS, there were about 149,000 (70 percent of the Pharmacy Plus target population) persons with incomes within this range. We do not have resource information to know how many of these persons would meet the Part D low-income assistance resource requirements.

As described above, Pharmacy Plus waivers must achieve "budget neutrality" by the end of the 5-year demonstration period. Savings to finance the prescription drug coverage for seniors are to be achieved by reducing the number of persons enrolling in the regular Medicaid program or reduce utilization of Medicaid acute, chronic and long-term care services for elderly persons.

States, such as Illinois and Wisconsin that have approved Pharmacy Plus waivers, forecast that they would achieve necessary savings by either diverting persons from their Medicaid nursing home program or from their entire Medicaid program. It is assumed that providing prescription drug coverage to low-income seniors will divert some seniors by reducing the deterioration rate of their health status and reduced income due to high medical expenses.[3]

To date, only 4 of 16 states have obtained an approved waiver, while 5 have either withdrawn their application or have disapproved waivers due to budget neutrality. Given that there will be a Medicare Part D coverage and that up to 70 percent of Washington's target population may be eligible for low-income assistance, we believe that it would now be very difficult to achieve budget neutrality by providing financial assistance to persons with income between 150 and 200 percent of FPL, which is about 51,000 (24 percent) of the 213,000 target population.

---

[3] Section V (page 18) of the CMS Pharmacy Plus application template.

Achieving budget neutrality is further complicated by time limits. In reviewing the four states with approved waivers, all four states estimate they will only achieve budget neutrality in the last year of the five-year demonstration period. Under existing SB 6088 provisions, DSHS would terminate the Medicaid prescription drug assistance program by December 2006. Assuming that the department was able to obtain an approved waiver and implement a program by July 2004, the state would only have two and one-half years to achieve budget neutrality.

## PHARMACY PLUS WAIVER STATUS

In July 2003, CMS staff informally told DSHS that it would be advisable to delay submitting a Pharmacy Plus waiver application until after Congress completed its current deliberations on adopting Medicare prescription drug coverage. Given the recent enactment of the Act, CMS has not had time to rule on whether it would still entertain Pharmacy Plus applications.

Medicare Part D could replace having a Pharmacy Plus waiver. As outlined above, only about 5,000 (3 percent) of low-income seniors in Washington reported not having Medicare coverage that would qualify them for Part D coverage, and up to 149,000 (70 percent) of the Pharmacy Plus target population might qualify for low-income assistance.

The Act does not specifically address the status of Medicaid Pharmacy Plus waivers. The Act prohibits use of Medicaid FFP for full-benefit dual eligibles, but does not prohibit Medicaid financing of other Medicare beneficiaries with Part D coverage.

The Act does recognize that some states have pharmacy assistance programs. Under the Act, there will be a State Pharmaceutical Assistance Transition Commission. The Commission is directed to develop a proposal to address the transitional issues the state programs will encounter because of the enactment of Part D coverage. The Commission is to report its recommendations to the President and Congress by January 1, 2005.

## CHAPTER 29, LAWS OF 2003, E1 (SB 6088) RECOMMENDATIONS

DSHS has not yet developed recommendations on financing options for the Medicaid prescription drug assistance program. The department would need to obtain an approved Pharmacy Plus waiver to determine the state fund costs required to support the program. We will not be able seek a waiver until CMS is able to advise states on whether they would still entertain such waivers.

Given enactment of the Medicare Part D coverage and low-income assistance, we believe that the Legislature should reconsider whether to proceed with such a waiver. The Pharmacy Plus waivers and associated prescription drug discount card programs provide transitional or bridge programs until Medicare enacted prescription drug coverage. With enactment of a Medicare senior drug discount program within six-months and Part D coverage by January 2006, it may be better for DSHS to focus its efforts on implementation of its new Medicare obligations.

We look forward to discussions with policy and appropriation committees on what actions we should take at this time.

Sincerely,

DENNIS BRADDOCK
Secretary

cc: Governor Locke
Douglas Porter
Tom Fitzsimmons
Bill Alkire
Ree Sailors
Marty Brown
Wolfgang Optiz
Elise Greef

# Appendix II.

# Senior Drug Education Program/Pharmacy Connections Data

# Appendix II. - Senior Drug Education Program/Pharmacy Connections Data

| SENIOR DRUG EDUCATION REPORTING SYSTEM | | |
|---|---|---|
| **Name of AAA:** | All participating AAAs | Total 2004 to date |
| **Training** | | |
| Number of Trainings Completed | | 275 |
| Number of Volunteer Trainers (Pharmacist, Other Health Care Professionals, etc.) | | 222 |
| Number of Seniors Trained | | **7,138** |
| Follow-up with Seniors With Significant Medication Management Concerns | | 34 |
| **Location of Training** | | |
| ☑ Senior Center | ☑ AAA Office | ☑ Non-Profit Partner | ☑ Community Center |
| ☑ SHIBA Sponsor | ☑ County/City Building | ☑ Hotel/Conf. Center | ☑ Other |

# Appendix II. - Senior Drug Education Program/Pharmacy Connections Data

| PHARMACY CONNECTION REPORTING SYSTEM | | |
|---|---|---|
| **Name of AAA:** | **Total of all reporting AAAs** | Jan-Nov 2004 |
| **Number of Information Calls Received** | | |
| **Type of Information Requested:** | | |
| General Information | | 2,666 |
| Discount Drugs | | 5,126 |
| Pharmaceutical Assistance Program | | 6,022 |
| Insurance Information & Questions | | 384 |
| Medicare Prescription Drug Questions | | 982 |
| **Total Information Calls Received** | | **15,180** |
| **Assistance Provided** | | |
| Discount Drug Application | | 2,393 |
| Pharmaceutical Assistance Program Applications/Coordination | | 6,703 |
| General Information | | 623 |
| Direct Involvement with Physician's Office or Other Health Care Professional | | 779 |
| Insurance Information/Clarification | | 83 |
| Medicare Prescription Drug Information | | 803 |
| Other: Describe Assistance | | 16 |
| **Total Assistance Provided** | | **11,400** |
| **Results (If Possible)*** | | |
| Persons Enrolled in Pharmaceutical Assistance Program | | 617 |
| Persons Who Received Discount Drug Cards | | 538 |
| Persons Who Received Insurance Information/Clarification | | 218 |
| Persons Who Received Medicare Prescription Drug Information | | 422 |

*** Follow up was not required**

# Appendix II. - Senior Drug Education Program/Pharmacy Connections Data

## As reported by the
## Washington State Office of the Insurance Commissioner

STATEWIDE HEALTH INSURANCE BENEFITS ADVISORS
(SHIBA) HELPLINE
Pharmacy Connection Program Grant
December 1, 2003 – September 30, 2004

DSHS Contract #0361-38868
Program Contract #21041167

### Data Collection Summary

| | **Totals** |
|---|---|
| Estimated # of Individual Client Contacts related to Prescription drugs or access | 15,519 |
| Estimated # of OIC/SHIBA HelpLine Web site hits related to Prescription drugs or access | 11,014 |
| **Total consumers w/ drug access-related issues served** | **26,533** |
| # of times Prescription-related subjects were covered for Group Public Presentations and Media Events | 627 |
| SHIBA Prescription Publications Distributed (27 versions) | 70,691 |
| Estimated # of current SHIBA Volunteers/Counselors | 300 |

# Appendix III.

# Prescription Drug Program Background Documents and Data

## Appendix III. - Prescription Drug Program Background Documents and Data

### Summary Overview of the Evidence-Based Review Process

**OHSU EPC**

- Manufacturers submit data
- Stakeholder input
- Literature Search
- Peer Review
- Draft Report released
- Stakeholder input and peer review
- Final Report

↓

**PDP Staff**

- Report distributed to P&T Committee and stakeholders
- 30 day notice of P&T Meeting
- MAA Supplemental Rebate bid request (must be received by MAA 7 days prior to meeting)

↓

**P&T Committee**

- Stakeholder input
- P&T Committee review and recommendation

↓

**PDP Staff**

- Review Supplemental Rebate bids
- Cost Analysis and recommendation to agency directors

↓

**Agency Directors**

- Final decision on Preferred Drug in reviewed class
- Notify Stakeholders, P&T Committee, and Endorsed Practitioners

↓

**Preferred Drug List**

- Implement

# Appendix III. - Prescription Drug Program Background Documents and Data

## Washington Prescription Drug Program's Preferred Drug Cost Analysis and Selection Process

**(November 16, 2004)**

## I. Purpose:

To establish a consistent methodology for the Uniform Medical Plan, Medical Assistance Administration and Labor & Industries (the agencies) to use when selecting a preferred drug within a therapeutic class.

## II. Scope:

This methodology applies to selection of preferred drugs for the drug classes to be included on the State of Washington Preferred Drug List (PDL). Drugs purchased through managed care contracts are not included in the analysis and are not within the scope of this document.

## III. Background:

RCW 70.14.050 authorizes the agencies to collectively determine the preferred drug(s) in a class based on the scientific evidence of efficacy and safety. For drugs with similar efficacy and safety, but with no differences when considered in special populations, the agencies have developed the following process that determines which drug(s) in a class are the lowest net cost to the state of Washington.

## IV. Determining the Average Daily Cost:

1) Each agency will keep a record of the average daily cost (ADC) (see formula below) and drug "unit" utilization for each drug in a class.

a. The third party will compute the ADC for each drug in the PDL class using the following steps:

b. Each state agency will provide the following data for each National Drug Code (NDC):
   i. NDC
   ii. Drug name
   iii. Units dispensed
   iv. Per unit ingredient price
   v. Per unit federal and state rebates (proprietary and confidential)
   vi. Days supplied

vii. Although not needed for the ADC calculation, each agency will also provide the number of scripts written by NDC for the computation of administrative costs and copay values described below

c. Total Net Cost by NDC is computed as Units x (Per Unit Ingredient Price – Per Unit Rebates).

d. Total Net Cost by candidate PDL drug is computed as the sum of total net costs by NDC for all NDCs for that PDL drug.

e. Total Days Supplied by candidate PDL drug is computed as the sum of all days supplied by NDC for all NDCs for that PDL drug.

f. ADC for each candidate PDL drug is computed as total net cost divided by total days supplied.

- The prices used to compute the ADC will be the most recent available, for example MAA prices are updated on a weekly basis.

- Utilization information will be based on the most recent 12-24 months of utilization data available. After the initial PDL determinations are made, updates will be based on the most recent available calendar quarter of data.

- Agency staff recognizes that historical utilization data may not reflect future trends for many reasons, among them significant price changes, impact on the market of new entries within a particular or related category of drug, and patent status changes. Agency staff also recognizes that historical information, absent other information, is the best predictor of future utilization given that actuarial and other technical adjustments are made as required.

- Utilization data for a new generic will use the associated brand's utilization as a proxy for the generic equivalent in PDL selection and potential net savings calculations.

- Utilization data will be used in the recommendation process for two basic purposes: First, to model relative shares of individual NDC demand within each drug; e.g. the use of 5mg tabs rather than 20mg tabs of a particular drug. Second, the data will provide an initial basis to estimate savings to the State under various scenarios.

2) MAA's average daily cost calculations for brand name (and certain generic) drugs include:

- State and federal rebate amounts paid for the drug(s); and
- A Maximum Allowable Cost (MAC) which may be set for generic and brand drug(s). MAC means the maximum amount that the MAA pays for a specific dosage form and strength of a multiple-source drug product.
- The following principles will guide MAA's ranking of a drug that has a MAC (Automated Maximum Allowable Cost (AMAC), State Maximum Allowable Cost "SMAC", or Federal Upper Limit "FUL"):
- Generics with or without a MAC will be included in Exhibit 1 and 2 when it will encourage equally effective and less costly utilization.
- Brand name drugs with a MAC will be included in Exhibit 1 however not included in the PDL selection when it will negatively affect the MAC program by increasing the number of MAC waivers.
- MAA – Division of Medicaid Management (DMM) pharmacy staff will announce future PDL classes to MAA – Division of Business and Finance (DBF) pharmacy staff in advance of the PDL selection in order to allow them to research and set state MAC prices where possible.

3) MAA, UMP, and L&I will send their respective average daily cost information to an agreed upon third party to maintain contractually required unit pricing confidentiality for analysis.

## V. Determining the Lowest Net Cost to the State:

1) The third party will model administrative (Prior Authorization (PA)) costs, Co-Payments (where applicable), substitution and intra-agency pricing differentials for each drug.

# Appendix III. - Prescription Drug Program Background Documents and Data

a. The administrative cost assumptions and methodology are as follows:

   For MAA and L&I, PA administrative costs have been estimated at $15 and $20 per call, respectively. These estimates are based on analysis performed by MAA and vendor pricing provided by L&I. Using actual call frequencies and prescription counts for the period April 2004 – July 2004 provided by MAA, the third party correlated the PA frequency to the number of non-preferred scripts (where the number of PA calls was approximately 20% of the number of non-preferred scripts). Administrative costs are estimated as the number of non-preferred scripts multiplied by 20% and then multiplied by the per call charge.

   No administrative costs are included for UMP.

b. The Co-Payment assumptions and methodology is as follows:

   ADC amounts are reduced by modeled co-payments. For each NDC, UMP provided an assumption of retail or mail order, from which it was assumed that retail drugs were prescribed in a 30 day supply and mail order drugs were prescribed in a 90 day supply. The Total Days Supplied was also provided, which combined with the days prescribed assumption, allowed for the estimation of the number of scripts written. The actual number of scripts written will be included in the data extract sent to the third party. Co-payment rules by tier and by retail/mail order were then applied to each drug.

   No co-payment reductions were applied to MAA or L&I.

c. The substitution and intra-agency pricing differential impacts are as follows:

   For each PDL scenario, those non-preferred drugs that shift to preferred drugs are assumed to do so in proportion to the relative historical utilization of preferred drugs separately for each agency. For MAA, the percentage of non-preferred drugs assumed to shift to preferred drugs in the savings estimate is based on recent historical levels of preferred drug utilization in the four classes with such history. The two classes for which the PDL is new (skeletal muscle relaxants and urinary incontinence drugs) have assumed a 70% migration of non-preferred to preferred drugs (a percentage slightly better than long-acting opioids). For Estrogens, PPIs and Statins a 90% migration assumption has been used.

Substitution for UMP assumes no movement of non-preferred generics and 50% movement of non-preferred brand name drugs.

Substitution for L&I is assumed to mimic MAA.

Intra-agency pricing differentials are considered in the model as drugs in each class are ranked according to the composite average cost for all three agencies combined. This composite ADC uses historical utilization by agency as weights in this computation.

2) The third party will incorporate these impacts into the ADC to construct an adjusted or net cost ADC for each drug, for each agency. The assumptions and methodology for the adjustment is as follows:

The model considers the co-payment adjusted UMP expenses as part of the initial ranking of drugs by class. Administrative costs and substitution rates are considered as part of the savings estimates associated with each PDL scenario by drug class.

3) The third party will, for each drug class and agency, rank order the ADC for each drug using a weighting relative to the lowest cost drug in a class, again assuring that federal and supplemental rebates are not disclosed.

Formula for weighting: Relative weight (RW) = (ADC for a Drug) / (ADC lowest drug)

4) The results will be arrayed from lowest cost to highest cost subject to the following categorical criteria. Within each therapeutic class, each drug will have a PDL eligibility status defined as one of the following five options:

1. Required for inclusion on the preferred drug list. In most cases this situation is the direct result of a P&T Committee decision (e.g. Lipitor®). It can also result from linkage to other contractual arrangements that make it financially impractical to offer any PDL that excludes the drug (e.g. Imitrex®).

2. Eligible for PDL inclusion. Generics and non-MAC brands are generally eligible for PDL inclusion (e.g. lovastatin).

3. Brands subject to MAC are identified and assumed not eligible for PDL inclusion (e.g. Mevacor®).

4. Excluded Drugs. Drugs identified by the P&T Committee as being excluded from eligibility for the PDL (e.g. Crestor®). These drugs are expected to have a very selective PA and minimal utilization.

5. P&T Committee selected drugs for specific medical conditions. Similar to Status 1 drugs in that the P&T Committee has directed their inclusion. However, these drugs differ in the model because they address a specific medical condition (e.g. Pravachol®). Therefore, the model assumes their inclusion in the PDL but excludes them from any utilization shifting assumptions as part of the savings estimates.

This status identifier (1-5) will be provided by MAA and is included in Exhibit I for each drug, which ranks drugs by status and the all agency combined ADC.

5) The results will be displayed in a format similar to the example below (See table #1)

## Exhibit 1: Average Daily Costs Rankings

| Drug Class/Status | Average Daily Agency Costs Rankings* | | | | Annualized Days Supplied | | | |
|---|---|---|---|---|---|---|---|---|
| | MAA | UMP | L&I | Combined | MAA | UMP | L&I | Combined |
| Drug/ 1 | | | | | | | | |
| Drug/ 2 | | | | | | | | |
| Drug/ etc. | | | | | | | | |

*** Exclusive of dispensing fees and pharmacy charges; inclusive of federal and state rebates. The ADC calculations include UMP co-payments.**

## VI. Decision Methodology to Choose Preferred Drugs in a Class:

While having a single preferred drug in a class will usually result in the lowest net cost to the state, other issues related to agency business needs, clinical and P&T Committee requests, WAC's and RCW may require increasing the number of drugs in a preferred class.

Agency staff recognizes that these constraints, clinical information and common sense will require that adjustments be made on a drug by drug basis. All drugs on the PDL must:

- ∉ Be among the categories of drugs that have been reviewed by the Oregon Health & Sciences University Drug Effectiveness Review Project that in which Washington participates.

- Be ranked consistent with any direction given by the Washington State P & T Committee.
- Exclude brands with generics that have an MAC for the calculations of ADC.

For all drugs within a class that meet the above initial selection requirements the agency staff shall use the tabular data described above and two summary exhibits created by the third party to assist in the decision process. Those exhibits are as follows:

- Exhibit I will display the ranking of drugs using the RW- ADC price of each drug and the historical utilization for that drug.

In situations where new drugs or other changes will impact future utilization those shall be noted and any adjustments documented.

In situations were the P & T Committee has made specific recommendations for specific drug(s), they will be added to the top of the list.

- Exhibit II will display the results of a savings impact analysis by conducting a savings impact analysis using the adjusted ADCs with offsets for administrative costs.

Exhibit II shows the agency savings, administrative costs and net savings to the state by adding an additional drug in order from the lowest to the highest net cost generic. Subtracting the agency administrative costs from the gross agency savings results in net agency savings. Combining each agency determines net state savings. The drug(s) resulting in the highest net state savings is moved forward for PDL Selection.

In situations where new drugs or other changes will impact future utilization those shall be noted and any adjustments documented based on brand equivalent utilizations.

The third party shall report saving impacts, again assuring unit cost confidentiality.

# Appendix III. - Prescription Drug Program Background Documents and Data

## Exhibit 2: Savings Relative to Increasing Access to Generic/Brand and Switching

| Drug | SAVINGS | | | | | | |
|---|---|---|---|---|---|---|---|
| | State | Gross Savings | | | –Net Savings | | |
| | WA | MAA | UMP | L&I | MAA | UMP | L&I |
| Drug | | | | | | | |
| Drug | | | | | | | |
| Drug | | | | | | | |
| Drug | | | | | | | |

*** Savings assume difference between shifting percentage of non-preferred drugs to preferred.**

## VII. Agency Staff Recommendations on Preferred Drugs:

Agency staff recommendations of preferred drugs will be based on reviews of:

- The data presented for cost analysis.
- The methodologies and assumptions used in the cost analysis.
- Buying access assumptions (e.g. % brand/generic).
- Consistency with DUR/P&T/Clinical requirements.

Agency staff will make preferred drug recommendations to agency heads using information from these deliberations to determine the lowest net cost to the State.

Agency staff will produce a recommendation summary that includes the following information for each drug class reviewed by the P&T Committee:

- A list of drugs in the therapeutic class under consideration, both generic and brand name.
- A copy of the P&T Committee motion and recommendation for the drug class.
- A recommendation as to the specific drug, or drugs to be included as preferred in the class.
- A summary table representing the combined cost analysis data contained in exhibits 1 and 2 above, with proprietary and confidential MAA rebate information redacted (Exhibit 3 below):

# Appendix III. - Prescription Drug Program Background Documents and Data

## Exhibit 3: Summary Cost Analysis by Drug Status/Relative Daily Cost

| Status | Drug Class | Days Supply* | | | | Relative Daily Cost -Net Copays |
|---|---|---|---|---|---|---|
| | Drugs | MAA | UMP | L&I | Combined | Combined |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | *Total -* | | | | | |

*** note on data used to calculate days supply**

Agency heads will determine the preferred drug(s) in a therapeutic class based on the agency staff analysis and recommendations.

The agency staff recommendation summary that has had all proprietary and confidential information redacted (Exhibit 3) will be a public document.

The P & T Committee will update its review and recommendations with regard to drug classes included on the PDL at least annually.

# Appendix III. - Prescription Drug Program Background Documents and Data

## Prescription Drug Program Agency Staff Analysis and Recommendations:

**Proton Pump Inhibitor Drug Class 10/29/2004**

### *Drugs in class*

| Generic | Brand |
|---|---|
| esomeprazole | Nexium® |
| lansoprazole capsule, powder | Prevacid® |
| lansoprazole solutab | P[illegible] Sol[illegible]Tab® |
| omeprazole capsules | [illegible]ilosec |
| omeprazole tablets | [illegible]ilosec [illegible]TC |
| pantoprazole | [illegible]otonix |
| rabeprazole | A[illegible]iphex |

### *P&T Committee recommendati[illegible]s*

After considering the evide[illegible]e of safet[illegible]ffica[illegible]y [illegible]nd sp[illegible]cial populat[illegible], I move that rabeprozole, omepr[illegible]zole, la[illegible]prazole, [illegible]a[illegible]top[illegible]zo[illegible], an[illegible]esomeprazole are safe, efficacious and ha[illegible] no diff[illegible]ces in a[illegible]ve[illegible]e [illegible]ven[illegible] in [illegible]ecial populations. They can be subject to t[illegible]erapeu[illegible]c interc[illegible]n[illegible] in the Wa[illegible]i[illegible]gton [illegible]ref[illegible]red drug list. A pediatric formul[illegible]ion [illegible]eeds [illegible]o be incl[illegible]ded [illegible]n the [illegible]Vash[illegible]gton [illegible]eferred Drug List. [Reese, Bray 2nd [illegible]ed u[illegible]nir[illegible]ous, Whi[illegible] abs[illegible]t.]

### *[illegible]ost analysis*

| Status | PPIs | Days Supply* | | | | Relative Daily Cost -Net Copays |
|---|---|---|---|---|---|---|
| | Drug | MAA | UMP | L&I | Combined | Combined |
| 2 | PRIL[illegible]SEC OTC | 2,601,404 | 86,266 | 22,744 | 2,710,414 | 1.00 |
| 2 | PREV[illegible]CID C[illegible]AP[illegible]ULE | 2,471,202 | 306,030 | 35,222 | 2,812,454 | 1.59 |
| 2 | PROT[illegible]NI[illegible] | 4,799,606 | 519,614 | 29,976 | 5,349,196 | 2.00 |
| 2 | ACIPH[illegible] | 0 | 147,072 | 7,450 | 154,522 | 3.38 |
| 2 | NEXIUM | 992,210 | 490,948 | 30,058 | 1,513,216 | 4.03 |
| 2 | OMEPRAZOLE RX | 163,612 | 683,982 | 16,372 | 863,966 | 4.50 |
| 3 | PRILOSEC | 68,408 | 59,724 | 6,554 | 134,686 | 7.63 |
| 5 | PREVACID POWDER | 0 | 1,640 | 0 | 1,640 | 4.08 |
| 5 | PREVACID SOLUTAB | 56,270 | 1,102 | 0 | 57,372 | 4.64 |
| | *Total - PPIs* | *11,152,712* | *2,296,378* | *148,376* | *13,597,466* | |

* **Days Supply derived from February 2004 – July 2004 experience, annualized**

EXAMPLE

# Appendix III. - Prescription Drug Program Background Documents and Data

## *Agency Staff recommendations*

After reviewing P&T recommendations and conducting a cost analysis the s
recommends the following drugs to be preferred on the Washington PDL:

**omeprazole tablets (Prilosec OTC ®)**
**lansoprazole tablets (Prevacid Solutab®)***
**lansoprazole capsules (Prevacid®)**
**lansoprazole powder (Prevacid®)***

*** subject to expedited prior authoriza on for ecial po lati s (pediatric/swallowing difficulties).**

### KEY TO DRU STA US N BERS

1. Required for inclusio on the pr ed ug ist. most cases s situation is the direct result f a P&T ommitt cisi n (e g. L pitor®). It can also result from linkage to o er cont ct al arra ge. en s th ma e it financially impractical to offe any PDL that ex lud s the d ug (e Imi ex®

   Eligibl for PDL incl sion. ene cs an non-MAC brands are generally eligible for PDL usion (e. lov in)

3. Brands sub to MA are ide ified and assumed not eligible for PDL inclusion (e g. Meva or

   Excluded rugs. rugs identified by the P&T Committee as being excluded from eligibility or the PDL (e.g. Crestor®). These drugs are expected to have a very selective A and minimal utilization.

5. Committee selected drugs for specific medical conditions. Similar to tatus 1 drugs in that the P&T Committee has directed their inclusion. However, these drugs differ in the model because they address a specific medical condition (e.g. Pravachol®). Therefore, the model assumes their inclusion in the PDL but excludes them from any utilization shifting assumptions as part of the savings estimates.

EXAMPLE

# Appendix III. - Prescription Drug Program Background Documents and Data

## Progress Report on Implementation of SB 6088

### Exhibit 1

### Percent of Prescriptions on Preferred PDL Drugs Dispensed

Provider compliance with the PDL varies by drug class and agency. The UMP allows its members a choice to pay a higher coinsurance or copay for a non preferred drug if they choose, which affects their rate of compliance to the PDL. Note the UMP compliance varies from a high of 91% in ACE Inhibitors to 21% in Long Acting Opioids.

Estrogens are not included in the MAA data as that drug class was implemented on December 1, 2004.

Of the twelve drug classes on the PDL, only five apply to L&I - Worker's Compensation: Long Acting Opioids; Skeletal Muscle Relaxants; Non-Steroidal Anti-inflammatory Drugs; Proton Pump Inhibitors; and Urinary Incontinence Drugs.

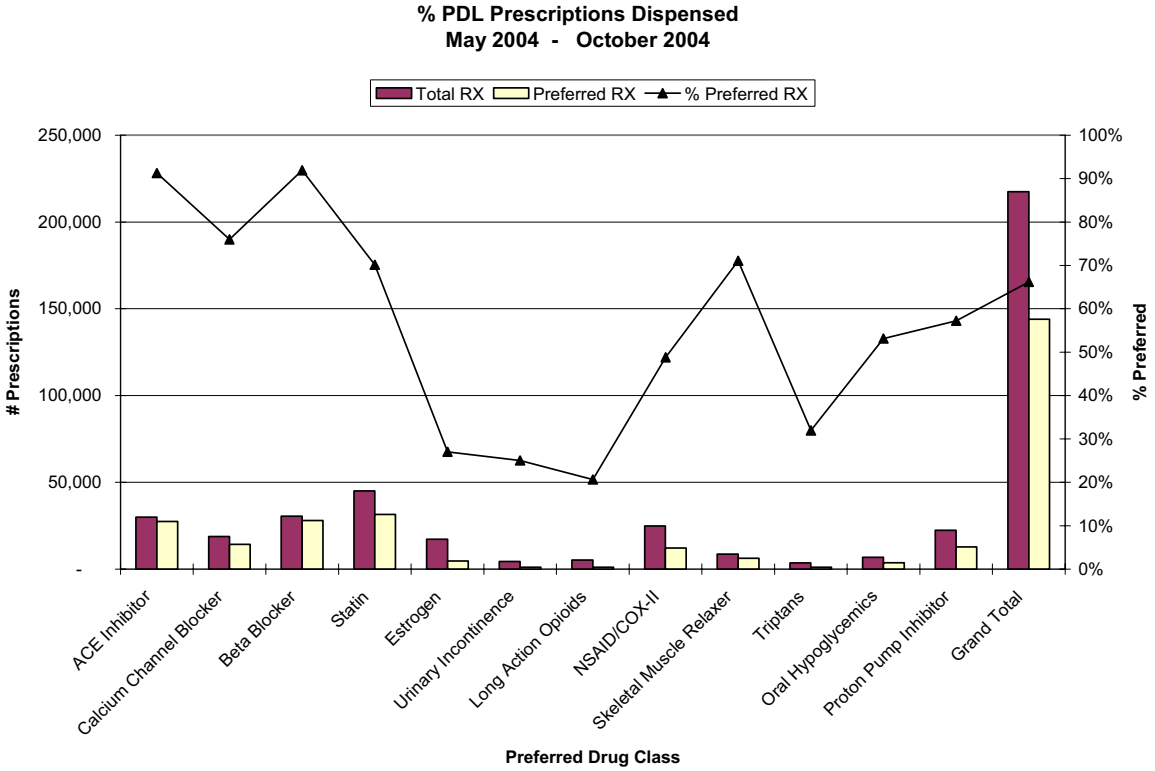
# Appendix III. - Prescription Drug Program Background Documents and Data

## HCA - Uniform Medical Plan

**Table 1**

| Drug Class | Total RX | Preferred RX | % Preferred RX |
|---|---|---|---|
| ACE Inhibitor | 29,973 | 27,356 | 91% |
| Calcium Channel Blocker | 18,792 | 14,280 | 76% |
| Beta Blocker | 30,448 | 27,979 | 92% |
| Statin | 45,041 | 31,600 | 70% |
| Estrogen | 17,129 | 4,631 | 27% |
| Urinary Incontinence | 4,373 | 1,094 | 25% |
| Long Action Opioids | 5,297 | 1,094 | 21% |
| NSAID/COX-II | 24,892 | 12,143 | 49% |
| Skeletal Muscle Relaxer | 8,687 | 6,174 | 71% |
| Triptans | 3,592 | 1,147 | 32% |
| Oral Hypoglycemics | 6,824 | 3,626 | 53% |
| Proton Pump Inhibitor | 22,393 | 12,816 | 57% |
| **Grand Total** | **217,441** | **143,940** | **66%** |

**Figure-1:**



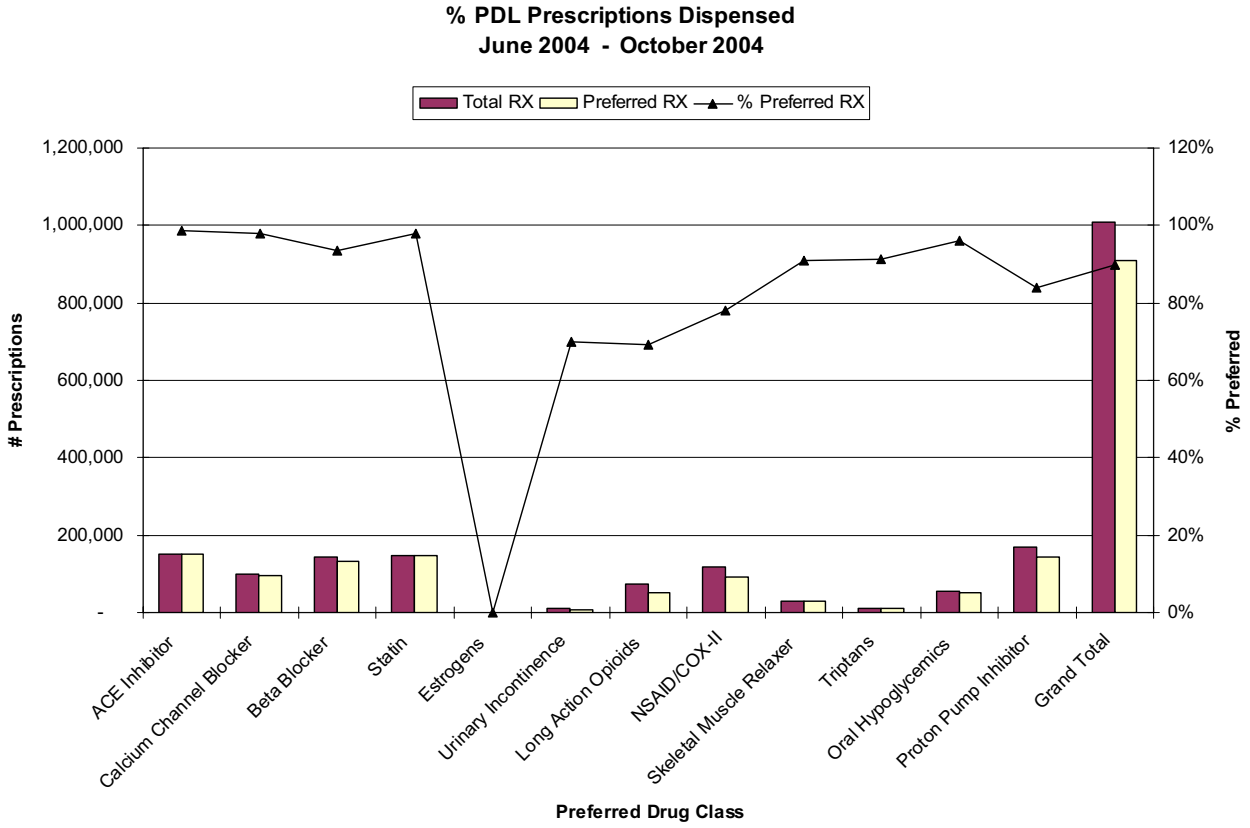
# Appendix III. - Prescription Drug Program Background Documents and Data

## DSHS – Medical Assistance Administration

**Table-2**

| Drug Class | Total RX | Preferred RX | % Preferred RX |
|---|---|---|---|
| ACE Inhibitor | 151,405 | 149,275 | 99% |
| Calcium Channel Blocker | 98,639 | 96,424 | 98% |
| Beta Blocker | 142,552 | 133,515 | 94% |
| Statin | 149,054 | 145,700 | 98% |
| Estrogens | - | - | 0% |
| Urinary Incontinence | 11,850 | 8,295 | 70% |
| Long Action Opioids | 73,132 | 50,559 | 69% |
| NSAID/COX-II | 118,224 | 92,158 | 78% |
| Skeletal Muscle Relaxer | 31,034 | 28,216 | 91% |
| Triptans | 10,453 | 9,525 | 91% |
| Oral Hypoglycemics | 53,639 | 51,445 | 96% |
| Proton Pump Inhibitor | 169,590 | 142,271 | 84% |
| **Grand Total** | **1,009,572** | **907,383** | **90%** |

**Figure-2**



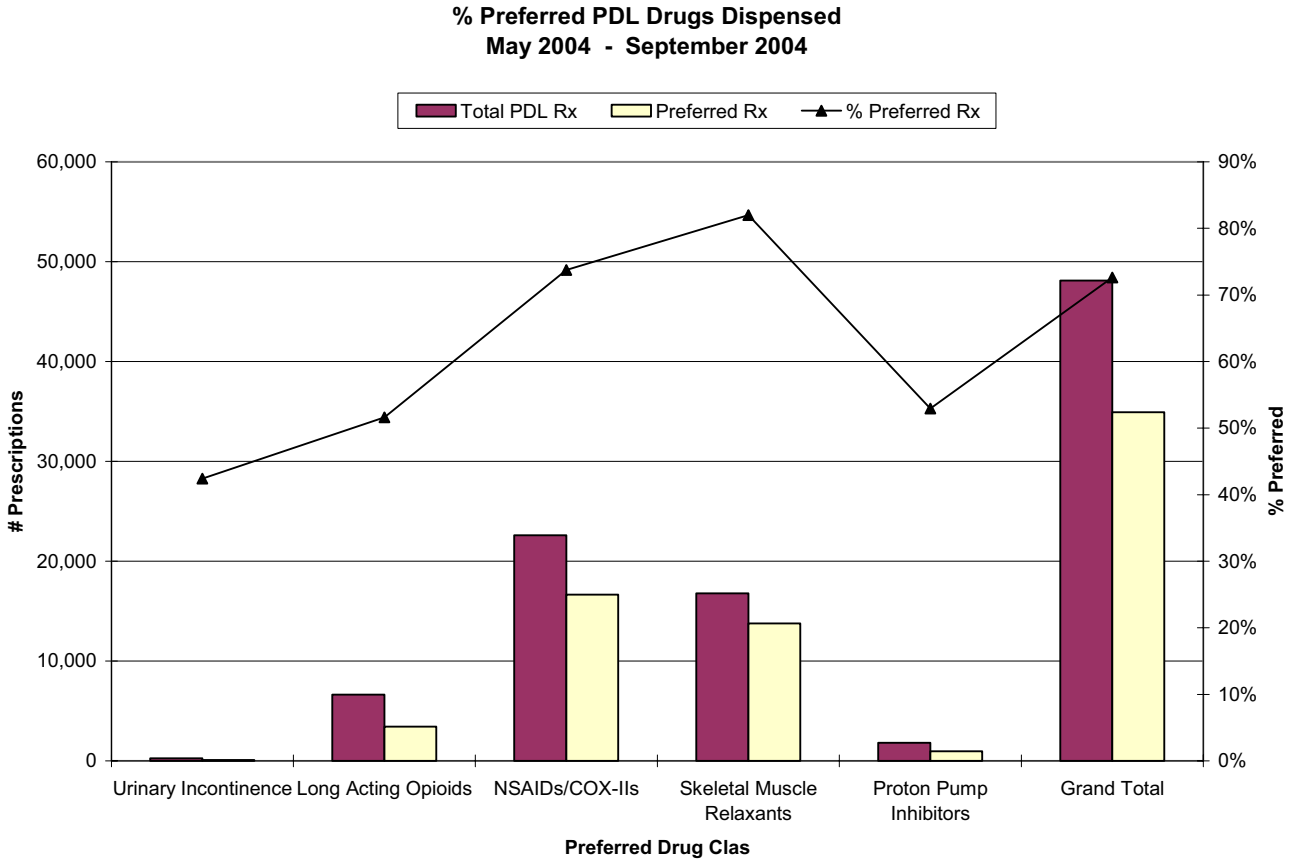
# Appendix III. - Prescription Drug Program Background Documents and Data

## L&I – Worker's Compensation Program

**Table-3**

| Drug Class | Total PDL Rx | Preferred Rx | % Preferred Rx |
|---|---|---|---|
| Urinary Incontinence | 250 | 106 | 42% |
| Long Acting Opioids | 6,641 | 3,427 | 52% |
| NSAIDs/COX-IIs | 22,600 | 16,669 | 74% |
| Skeletal Muscle Relaxants | 16,789 | 13,765 | 82% |
| Proton Pump Inhibitors | 1,833 | 970 | 53% |
| **Grand Total** | **48,113** | **34,937** | **73%** |

**Figure-3**



# Appendix III. - Prescription Drug Program Background Documents and Data

## Exhibit 2

### Percent of Prescriptions on Preferred Drug List signed Dispense as Written

The percent of prescriptions written by providers requesting dispense as written for the three agencies varies from 12%-30%.

The Long Acting Opioids have a high incidence of DAW. Although TIP has been implemented for this class, conversion has been slow. Federal law requires that a pharmacist receive a new paper prescription in order to dispense these medications.

# Appendix III. - Prescription Drug Program Background Documents and Data

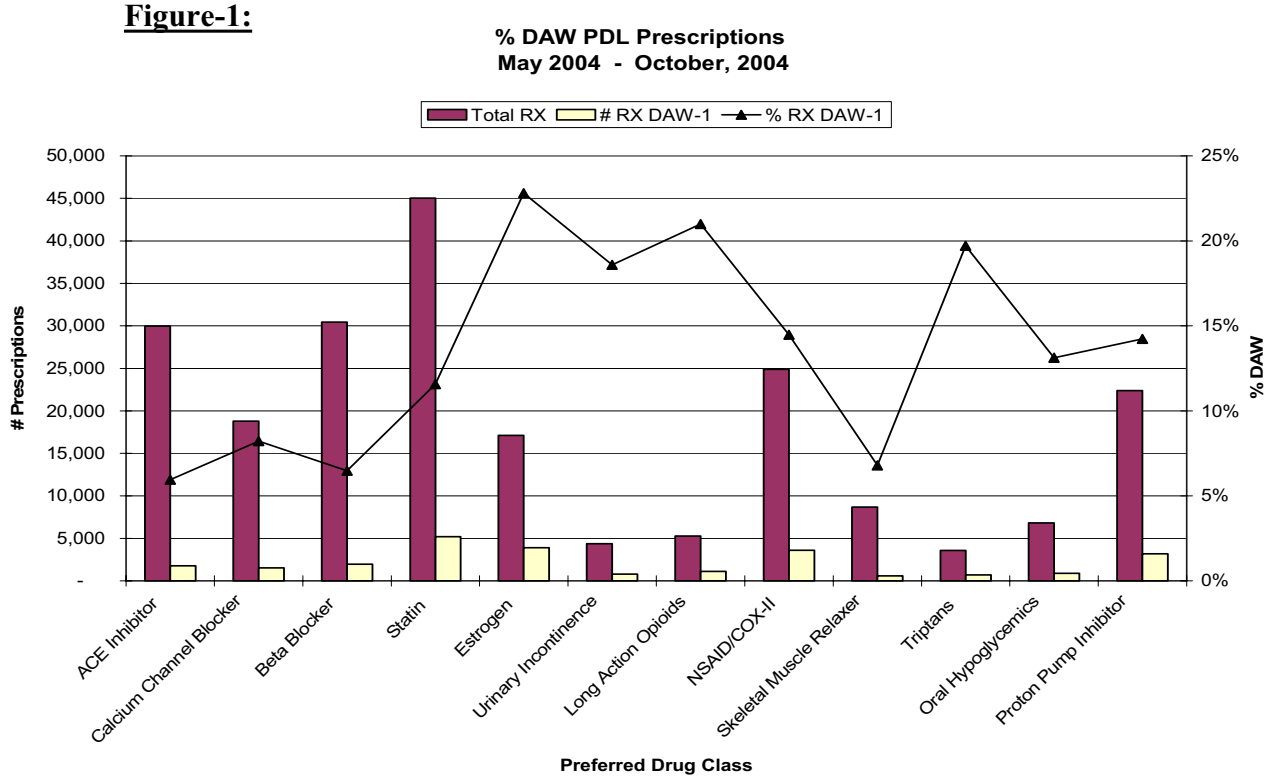
## HCA - Uniform Medical Plan

**Table 1**

| Drug Class | Total RX* | # RX DAW-1 | % RX DAW-1 |
|---|---|---|---|
| ACE Inhibitor | 29,973 | 1,786 | 6% |
| Calcium Channel Blocker | 18,792 | 1,544 | 8% |
| Beta Blocker | 30,448 | 1,973 | 6% |
| Statin | 45,041 | 5,210 | 12% |
| Estrogen | 17,129 | 3,907 | 23% |
| Urinary Incontinence | 4,373 | 813 | 19% |
| Long Action Opioids | 5,297 | 1,112 | 21% |
| NSAID/COX-II | 24,892 | 3,605 | 14% |
| Skeletal Muscle Relaxer | 8,687 | 590 | 7% |
| Triptans | 3,592 | 708 | 20% |
| Oral Hypoglycemics | 6,824 | 896 | 13% |
| Proton Pump Inhibitor | 22,393 | 3,187 | 14% |
| **Grand Total** | **217,441** | **25,331** | **12%** |

***Total of all prescriptions regardless of endorsing status of the prescriber**

**Figure-1:**



# Appendix III. - Prescription Drug Program Background Documents and Data

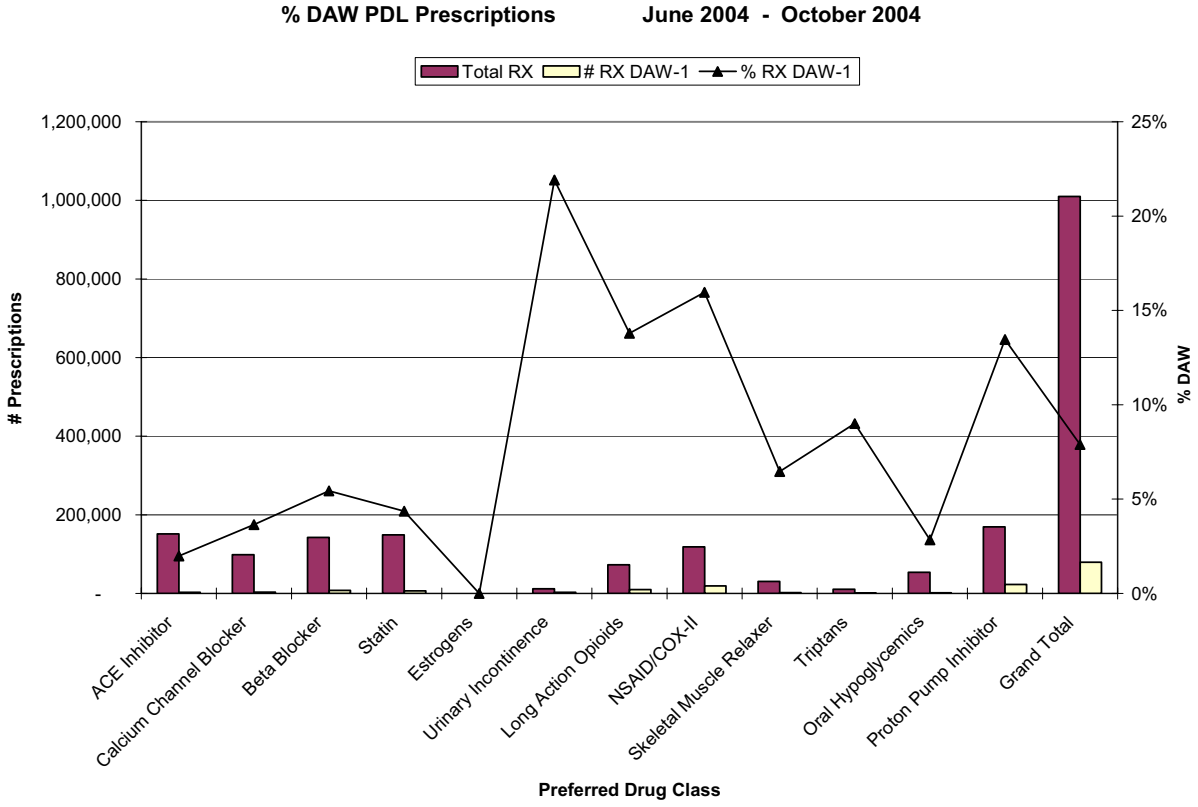
## DSHS – Medical Assistance Administration

**Table-2**

| Drug Class | Total RX * | # RX DAW-1 | % RX DAW-1 |
|---|---|---|---|
| ACE Inhibitor | 151,405 | 3,013 | 2% |
| Calcium Channel Blocker | 98,639 | 3,599 | 4% |
| Beta Blocker | 142,552 | 7,756 | 5% |
| Statin | 149,054 | 6,500 | 4% |
| Estrogens | - | - | 0% |
| Urinary Incontinence | 11,850 | 2,596 | 22% |
| Long Action Opioids | 73,132 | 10,083 | 14% |
| NSAID/COX-II | 118,224 | 18,872 | 16% |
| Skeletal Muscle Relaxer | 31,034 | 2,008 | 6% |
| Triptans | 10,453 | 941 | 9% |
| Oral Hypoglycemics | 53,639 | 1,523 | 3% |
| Proton Pump Inhibitor | 169,590 | 22,830 | 13% |
| **Grand Total** | **1,009,572** | **79,721** | **8%** |

***Total of all prescriptions regardless of endorsing status of the prescriber**

**Figure-2**



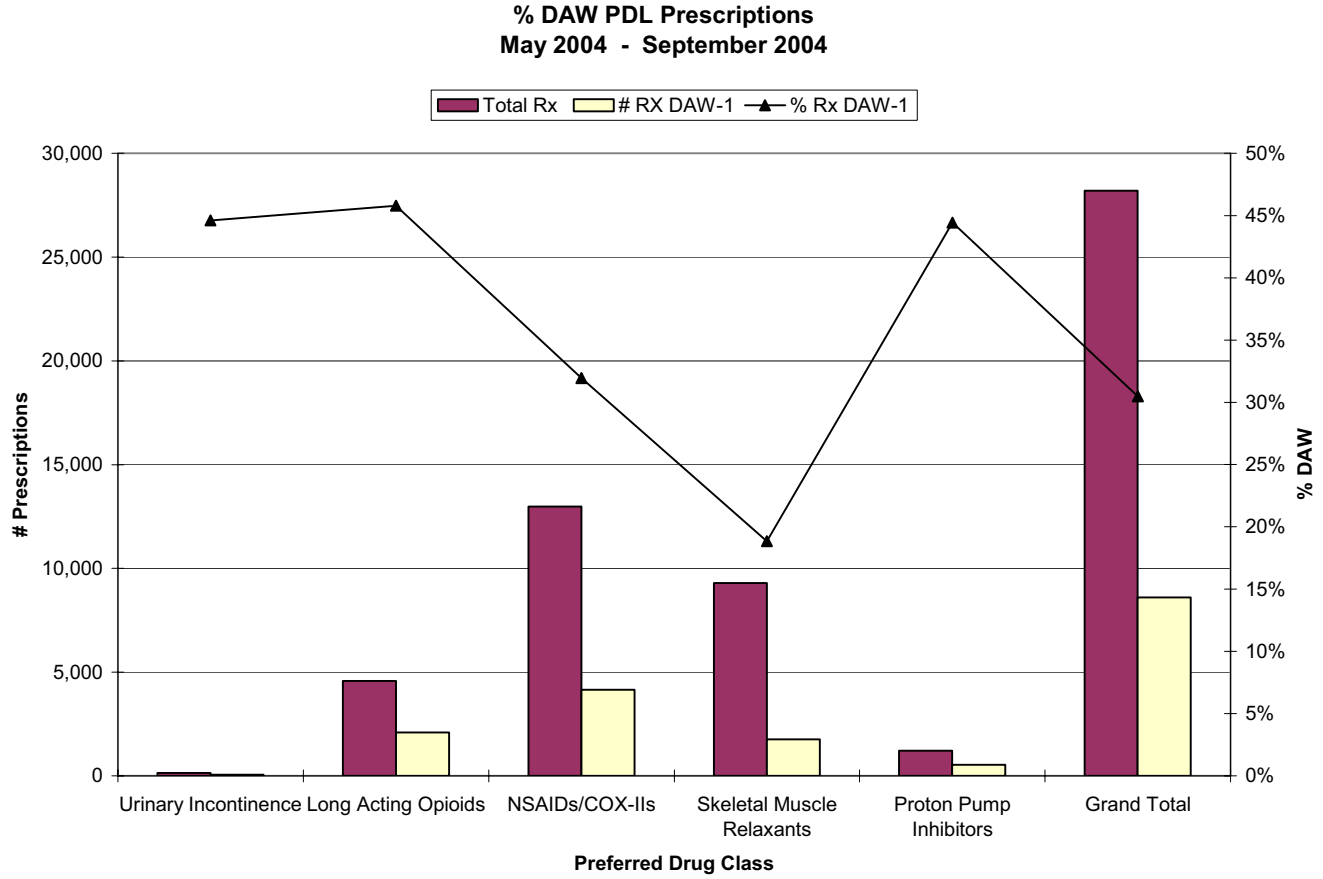
# Appendix III. - Prescription Drug Program Background Documents and Data

## L&I – Worker's Compensation Program

**Table-3**

| Drug Class | Total Rx by Endorsing Practitioner | # RX DAW-1 | % Rx DAW-1 |
|---|---|---|---|
| Urinary Incontinence | 139 | 62 | 45% |
| Long Acting Opioids | 4,572 | 2,094 | 46% |
| NSAIDs/COX-IIs | 12,983 | 4,148 | 32% |
| Skeletal Muscle Relaxants | 9,295 | 1,751 | 19% |
| Proton Pump Inhibitors | 1,213 | 539 | 44% |
| **Grand Total** | **28,202** | **8,594** | **30%** |

**Figure-3**



# Appendix III. - Prescription Drug Program Background Documents and Data

## Exhibit 3

### Percent of Prescriptions on Preferred Drug List Prescribed by Endorsing Practitioners

There is a large discrepancy between the UMP and the two other agencies in measuring the percent of prescriptions on the PDL prescribed by endorsing practitioners. This difference is most likely due to the inability of the prescription claims processing system, used by UMP's pharmacy benefit manager, to identify endorsing practitioners by means other than the prescriber's Drug Enforcement Agency (DEA) number. Since the percentage of endorsing practitioners for MAA and L&I is similar we believe this accurately reflects the participation of our providers. We believe having over half of the providers participating in the endorsing practitioners program is a measurement of success in recruiting them to participate.

# Appendix III. - Prescription Drug Program Background Documents and Data

## Exhibit 3

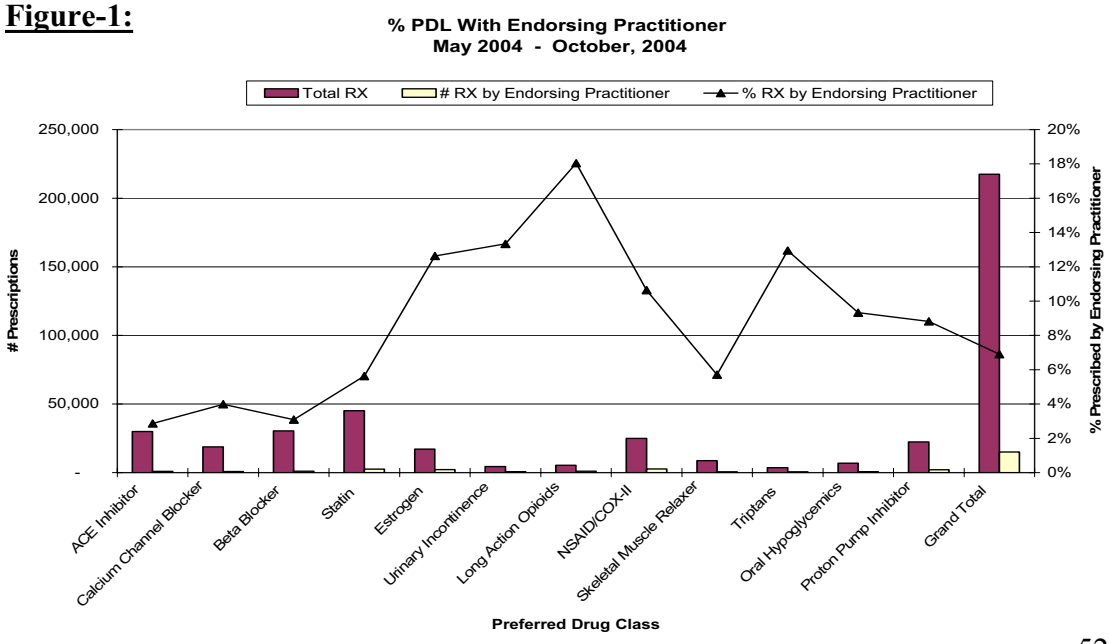
### Percent of Prescriptions on Preferred Drug List Prescribed by Endorsing Practitioners

## HCA - Uniform Medical Plan

**Table 1**

| Drug Class | Total RX | No. RX by Endorsing Practitioners | % RX by Endorsing Practitioners |
|---|---|---|---|
| ACE Inhibitor | 29,973 | 856 | 3% |
| Calcium Channel Blocker | 18,792 | 748 | 4% |
| Beta Blocker | 30,448 | 941 | 3% |
| Statin | 45,041 | 2,537 | 6% |
| Estrogen | 17,129 | 2,163 | 13% |
| Urinary Incontinence | 4,373 | 583 | 13% |
| Long Action Opioids | 5,297 | 956 | 18% |
| NSAID/COX-II | 24,892 | 2,648 | 11% |
| Skeletal Muscle Relaxer | 8,687 | 496 | 6% |
| Triptans | 3,592 | 465 | 13% |
| Oral Hypoglycemics | 6,824 | 636 | 9% |
| Proton Pump Inhibitor | 22,393 | 1,974 | 9% |
| **Grand Total** | **217,441** | **15,003** | **7%** |

**Figure-1:**



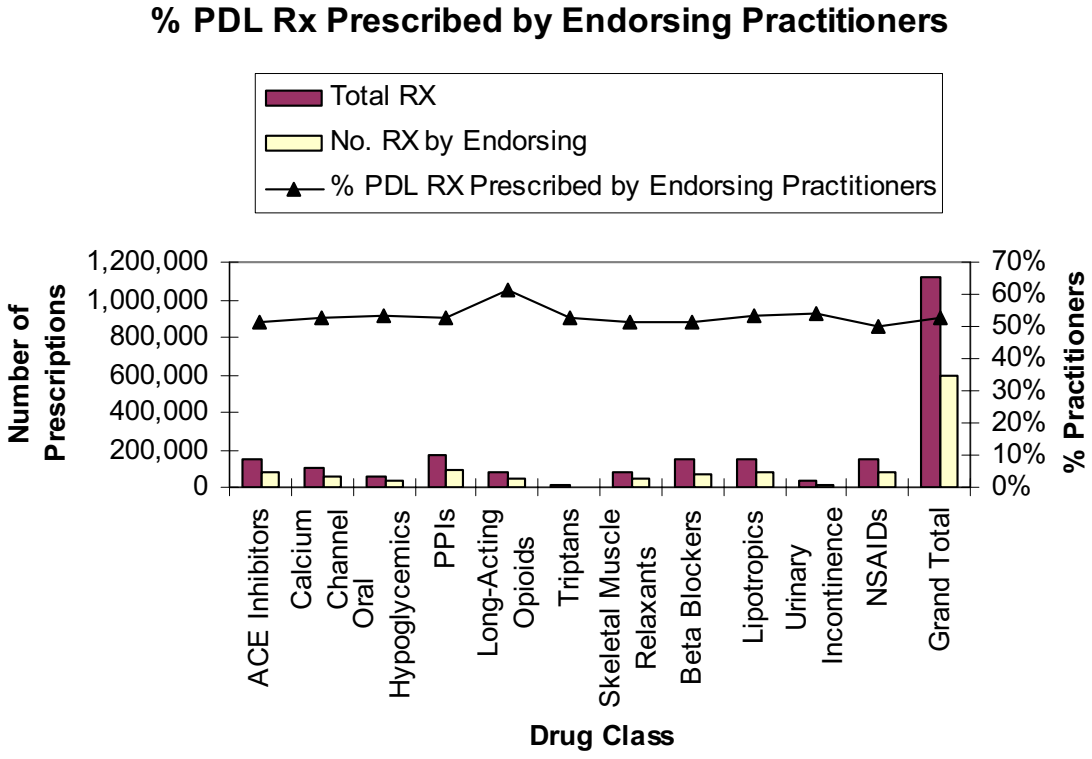
# Appendix III. - Prescription Drug Program Background Documents and Data

## DSHS – Medical Assistance Administration

**Table-2**

| Drug Class | Total RX | No. RX by Endorsing Practitioners | % PDL RX Prescribed by Endorsing Practitioners |
|---|---|---|---|
| ACE Inhibitors | 152,820 | 78,592 | 51% |
| Calcium Channel Blockers | 99,520 | 52,623 | 53% |
| Oral Hypoglycemics | 54,158 | 28,921 | 53% |
| PPIs | 170,570 | 90,288 | 53% |
| Long-Acting Opioids | 74,416 | 45,683 | 61% |
| Triptans | 10,462 | 5480 | 52% |
| Skeletal Muscle Relaxants | 83,614 | 43,029 | 51% |
| Beta Blockers | 144,127 | 73,575 | 51% |
| Lipotropics | 149,994 | 79,660 | 53% |
| Urinary Incontinence | 31,529 | 16,986 | 54% |
| NSAIDs | 151,895 | 75,766 | 50% |
| **Grand Total** | **1,123,105** | **590,603** | **53%** |

**Figure-2**



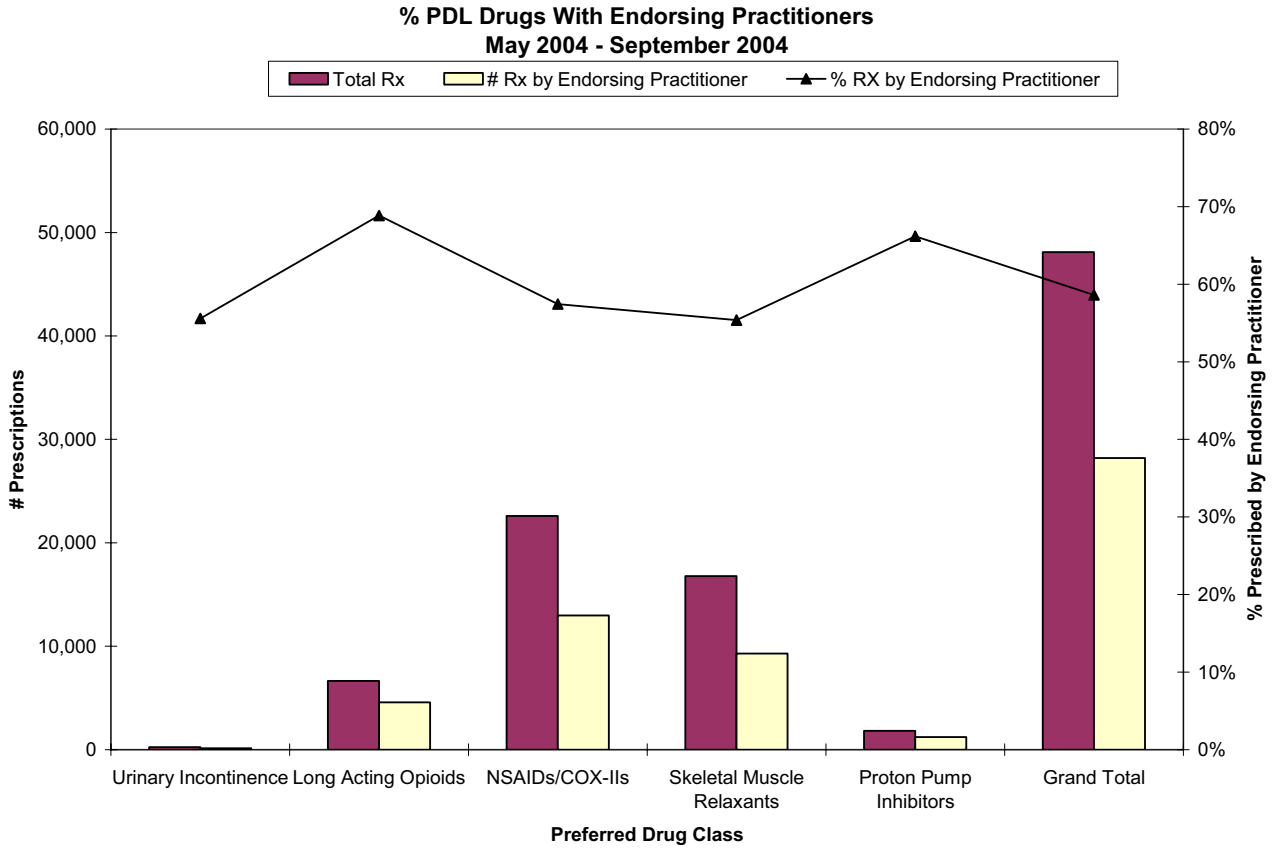
# Appendix III. - Prescription Drug Program Background Documents and Data

## L&I – Worker's Compensation Program

**Table-3**

| Drug Class | Total Rx | No. Rx by Endorsing Practitioners | % RX by Endorsing Practitioners |
|---|---|---|---|
| Urinary Incontinence | 250 | 139 | 56% |
| Long Acting Opioids | 6,641 | 4,572 | 69% |
| NSAIDs/COX-IIs | 22,600 | 12,983 | 57% |
| Skeletal Muscle Relaxants | 16,789 | 9,295 | 55% |
| Proton Pump Inhibitors | 1,833 | 1,213 | 66% |
| **Grand Total** | **48,113** | **28,202** | **59%** |

**Figure-3**



# Appendix III. - Prescription Drug Program Background Documents and Data

## Washington State Preferred Drug List
**as of December 2004**

### Musculoskeletal & Pain Medications

### *Nonsteroidal anti-inflammatory drugs (NSAID)*
### *Cyclo-oxygenase - 2 (Cox-II) inhibitors*

| NONPREFERRED BRAND NAME DRUGS | PREFERRED GENERIC ALTERNATIVES |
|---|---|
| Anaprox/DS (naproxen Sodium) | diclofenac potassium |
| Bextra (valdecoxib) | diclofenac sodium |
| Cataflam (diclofenac potassium) | etodolac/XL |
| Celebrex (celecoxib) | ibuprofen |
| Clinoril (sulindac) | ketoprofen |
| Daypro (oxaprozin) | nabumetone |
| Feldene (piroxicam) | naproxen/sodium |
| Lodine/XL (etodolac) | oxaprozin |
| Mobic (meloxicam) | piroxicam |
| Motrin (ibuprofen) | salsalate |
| Naprosyn/DS (naproxen) | sulindac |
| Orudis (ketoprofen) | |
| Oruvail (ketorprofen) | |
| Relafen (nabumetone) | |
| Salflex (salsalate) | |
| Voltaren/XL (diclofenac sodium) | |

### *Skeletal Muscle Relaxers*

| NONPREFERRED GENERIC DRUGS | PREFERRED GENERIC ALTERNATIVES |
|---|---|
| carisoprodol | baclofen |
| orphenadrine | chlorzoxazone |
| tizanidine | cyclobenzaprine |
| | methocarbamol |

**NONPREFERRED BRAND NAME DRUGS**

Dantrium (dantrolene)
Flexeril (cyclobenzaprine)
Lioresal (baclofen)
Norflex (orphenadrine)
Parafon Forte (chlorzoxaxone)
Robaxin (methocarbamol)

Skelaxin (Metaxalone)
Soma (carisoprodol)
Zanaflex (tizanidine)

### *Long Acting Opioids*

| NONPREFERRED GENERIC DRUGS | PREFERRED GENERIC ALTERNATIVES |
|---|---|
| levorphanol | methadone |
| | morphine sulfate SA/SR |
| **NONPREFERRED BRAND NAME DRUGS** | oramorph SR |
| Avinza (morphine sulfate ER) | |
| Duragesic (transdermal fentanyl) | |
| Kadian (morphine SR) | |
| Levo-Dromoran (levorphanol) | |
| MS Contin (morphine SR) | |
| Oxycontin (oxycodone ER) | |

### *Drugs to treat headaches (Triptans)*

| NONPREFERRED BRAND NAME DRUGS | PREFERRED BRAND NAME ALTERNATIVES |
|---|---|
| Amerge (naratriptan) | Imitrex Injection (sumatriptan) |
| Axert (almotriptan) | Imitrex Nasal Spray (sumatriptan) |
| Frova (frovatriptan) | Maxalt (rizatriptan) |
| Imitrex tablets (sumatriptan) | |
| Maxalt MLT (rizatriptan) | |
| Zomig/ZMT (zolmitriptan) | |

## Diabetes & Endocrine Drugs

### *Sulfonylureas and Meglitinides*

| NONPREFERRED GENERIC DRUGS | PREFERRED GENERIC ALTERNATIVES |
|---|---|
| chlorpropamide | glyburide |
| tolazamide | glipizide |
| tolbutamide | |
| **NONPREFERRED BRAND NAME DRUGS** | |
| Amaryl (glimeperide) | |
| Diabenese (chlorpropamide) | |

DiaBeta (glyburide)
Glucotrol (glipizide)
Glynase (glyburide micronized)
Tolinase (tolazamide)
Micronase (glyburide micronized)
Orinase (tolbutamide)
Prandin (repaglinide)
Starlix (nateglinide)

### *Estrogens*

| NONPREFERRED GENERIC DRUGS | PREFERRED GENERIC ALTERNATIVES |
|---|---|
| etradiol transdermal | estradiol oral/vaginal cream |
| estropipate | Preferred Brand Name Alternatives |
| | Menest (esterified estrogens) |
| **NONPREFERRED BRAND NAME DRUGS** | PremPro (conjugated estrogens/medroxyprogesterone) |
| Cenestin (synthetic conjugated estrogens) | |
| Climara (estradiol transdermal) | |
| Esclim (estradiol transdermal) | |
| Estrace oral (estradiol tablets) | |
| Estraderm (estradiol transdermal) | |
| Estring (estradiol vaginal ring) | |
| Femring (estradiol vaginal ring) | |
| Ogen (estropipate) | |
| Premarin oral/vaginal (conj. estrogens) | |
| Vagifem (estradiol vaginal tablets) | |
| Vivelle/DOT (estradiol transdermal) | |

## Gastrointestinal Medications

### *Proton Pump Inhibitors*

| NONPREFERRED BRAND NAME DRUGS | PREFERRED BRAND NAME ALTERNATIVES |
|---|---|
| Aciphex (rabepraxole) | Prilosec OTC |
| Nexium (esomeprazole) | Protonix (pantoprazole) |
| Omeprazole RX | |
| Prevacid (lansoprazole) | |
| Prilosec RX (omepraxole RX) | |

# Appendix III. - Prescription Drug Program Background Documents and Data

## Cardiovascular Medications

### *HMG-CoA Reductase Inhibitors (Statins) to lower cholesterol*

| NONPREFERRED BRAND NAME DRUGS | PREFERRED GENERIC ALTERNATIVES |
|---|---|
| Lescol/XL (fluvastatin) | Lovastatin |
| Mevacor (lovastatin) | |
| Zocor (simvastatin) | **PREFERRED BRAND NAME ALTERNATIVES** |
| | Lipitor (atorvastatin) |
| | Pravachol (pravastatin) |

### *Calcium Channel Blockers*

| NONPREFERRED BRAND NAME DRUGS | PREFERRED GENERIC ALTERNATIVES |
|---|---|
| Adalat/CC (nifedipine XR) | diltiazem/XR |
| Calan/SR (verapamil) | nifedipine/XR |
| Cardene/SR (nicardipine) | verapamil/XR |
| Cardizem/CD/LA/SR (diltiazem/XR) | |
| Cartia XT (diltiazem XR) | **PREFERRED BRAND NAME ALTERNATIVES** |
| Dilacor XR (diltiazem XR) | |
| Diltia XT (diltiazem XR) | |
| Dynacirc/CR (isradipine) | Norvasc (amlodipine) |
| Isoptin/SR (verapamil) | |
| Plendil (felodipine) | |
| Procardia/XL (nifedipine XR) | |
| Sular (nisoldipine) | |
| Taztia XT (diltiazem) | |
| Tiazac (diltiazem) | |
| Vascor (bepridil) | |
| Verelan/PM (verapamil) | |

### *Beta Blockers*

| NONPREFERRED BRAND NAME DRUGS | PREFERRED GENERIC ALTERNATIVES |
|---|---|
| Cartrol (carteolol) | atenolol |
| Coreg (carevedilol) | bisoprolol |
| Corgard (nadolol) | carteolol |
| Inderal/Inderal LA (propranolol) | labetalol |
| Levatol (Penbutalol) | metoprolol |
| Lopressor (metoprolol) | nadolol |

| | |
|---|---|
| Normodyne (labetalol) | penbutolol |
| Tenormin (atenolol) | pindolol |
| Trandate (labetalol) | propranolol |
| Visken (pindolol) | |
| Zebeta (bisoprolol) | **PREFERRED BRAND NAME ALTERNATIVES** |
| | Toprol XL (metoprolol succinate) |

### *Ace Inhibitors*

| **NONPREFERRED BRAND NAME DRUGS** | **PREFERRED GENERIC ALTERNATIVES** |
|---|---|
| Accupril (quinapril) | captopril |
| Aceon (perindopril) | enalapril |
| Capoten (captopril) | lisinopril |
| Lotensin (benazepril) | |
| Mavik (trandolapril) | **PREFERRED BRAND NAME ALTERNATIVES** |
| Monopril (fosinopril) | |
| Prinivil (lisinopril) | Altace (ramipril) |
| Univasc (moexipril) | |
| Vasotec (enalapril) | |
| Zestril (lisinopril) | |

## Genitourinary Medications

### *Drugs to treat urinary incontinence*

| **NONPREFERRED BRAND NAME DRUGS** | **PREFERRED GENERIC ALTERNATIVES** |
|---|---|
| Detrol/LA (tolterodine) | oxybutynin tablets/syrup |
| Ditropan/XL/syrup (oxybutynin) | |
| Oxytrol (oxybutynin transdermal) | |
| Urispas (flavoxate) | |

# Appendix IV.

# Pharmacy & Therapeutics Committee Information

# Appendix IV. - Pharmacy & Therapeutics Committee Information

## Current P&T membership:

### Robert Bray, M.D.
Dr. Bray is the assistant director for a family practice residency program, Family Medicine Spokane, Spokane, Washington. He has been in practice in the state of Washington since 1984 and is a member of the Washington State Medical Association.

### Carol Cordy, M.D. (Vice Chair)
Dr. Cordy is the site director for the Swedish Family Medicine Residency Program at the 45th St. Community Clinic in Seattle, Washington. She has been a member and co-chair of the Medical Assistance Administration's Drug Utilization and Education Council (MAA DUEC) since 2002. Because of this position she has extensive experience in evidence-based medicine.

### Daniel Lessler, M.D. Internal Medicine, (Chair)
Dr. Lessler is the associate medical director for Ambulatory Care Services at Harborview Medical Center, Seattle, Washington. Through Harborview he is active in the University of Washington's residency programs. Dr. Lessler has been a member of the MAA DUEC since 2003.

### T. Vyn Reese, M.D.
Dr. Reese is the section chief for General Internal Medicine, Madison Clinic, Pacific Medical Centers in Seattle, Washington. In addition to his added qualifications in Geriatric Medicine, Dr. Reese is the chair of the Pacific Medical Centers Pharmacy & Therapeutics committee and also is a member of PacifiCare's national formulary committee.

### Angelo Ballasiotes, Pharm.D.
Dr. Ballasiotes is a board certified psychiatric pharmacist practicing pharmacy with prescriptive authority to treat mentally ill and chemically affected patients at Central Washington Comprehensive Mental Health inpatient and outpatient program. Dr. Ballasiotes has previously owned a pharmacy as a private business owner. He is a member of the Yakima County Pharmacy Association.

### Alvin Goo, Pharm.D.
Dr. Goo is a clinical pharmacist at Harborview Medical Center, Department of Pharmacy and Family Medicine, Seattle, Washington. Through Harborview, he is active in University of Washington residency programs. He has been a member of the MAA DUEC for the past several years.

# Appendix IV. - Pharmacy & Therapeutics Committee Information

## Jason Iltz, Pharm.D.

Dr. Iltz is a Clinical Assistant Professor of Pharmacotherapy at Washington State University College of Pharmacy in Spokane, Washington. He is also a Clinical Pharmacy Specialist, Anticoagulation Clinic, at Group Health Cooperative in Spokane, Washington. Beginning his career with Washington State University and Group Health Cooperative in 1997, Dr. Iltz is a certified disease manager (CDM) with credentialing obtained through the National Institute for Standards in Pharmacist Credentialing (NISPC). Dr. Iltz is the past president and a current member of the Spokane Pharmacy Association.

## Janet Kelly, Pharm.D.

Dr. Kelly is the outcomes and cost management pharmacist at the University of Washington Medical Center in Seattle, Washington. She also has prescriptive authority to treat patients with diabetes seen in the Diabetes Care Center at University of Washington Medical Centers.

## John White, PA, Pharm.D

Dr. White is a Physician Assistant practicing primary care at the Indian Health Service Clinic, in Wellpinit, Washington. He is also a professor and Vice Chairman of Research for the Department of Pharmacotherapy at Washington State University. In addition, Dr. White is also a member of the Washington Academy of Physician Assistants.

## Patti Varley, ARNP

Ms. Varley is a Child and Adolescent Psychiatric Clinical Nurse Specialist at Childrens Hospital and Regional Medical Center, in Seattle, Washington. She has been a member of the MAA DUEC for the last few years. She is a member of AAPPN and ARNPs United and the Washington State Nurses Association.

# Appendix IV. - Pharmacy & Therapeutics Committee Information

**PLAN OF OPERATION and BYLAWS**
**PHARMACY & THERAPEUTICS COMMITTEE**
**(P&T COMMITTEE)**

This Pharmacy & Therapeutics Committee, its officers, members and any committees or working groups acting on behalf of the Committee shall recognize, observe and be bound by the provisions of this Plan of Operation and Bylaws.

The Pharmacy and Therapeutics Committee shall perform its functions in accordance with the requirements of RCW 70.14.050 (as amended 2003, or as hereafter amended), the Social Security Act, Title 19 § 1927, Chapter 41.05 RCW, this Plan of Operation and Bylaws (the Plan), as adopted or as may be hereafter amended. The Plan shall become effective upon approval in writing by the Appointing Authority.

**A. NAME:**

This entity shall be known as the Washington State Pharmacy and Therapeutics Committee (P&T Committee or Committee).

**B. AUTHORITY TO ACT:**

The P&T Committee is formed pursuant to RCW 70.14.050 (as amended, 2003[1]) to evaluate available evidence regarding the relative safety, efficacy and effectiveness of prescription drugs in a class and to make recommendations to state agencies regarding the development of a preferred drug list.

The Committee is a "technical review committee" established by the Appointing Authority to aid in the development, acquisition, or implementation of state-purchased health care. Pursuant to RCW 42.17.310(1)(eee)[2], information obtained by the Committee in pursuant of its duties may be exempt or withheld from public inspection and copying whether held by the HCA or the Committee.

**C. DEFINITIONS:**

1) "Act" means SB 6088, Ch. 29 Laws 1st Special Session, 2003, as may be codified.

[1] SB 6088, Ch. 29, Laws 1st Special Session, 2003.
[2] HB 1444, Ch. 277, Laws of 2003.

# Appendix IV. - Pharmacy & Therapeutics Committee Information

2) "Appointing Authority" means the agency heads of the Washington State Health Care Authority (HCA), Department of Social and Health Services (DSHS), and the Department of Labor and Industries (L&I), acting together. Any agency head may designate a representative to act on his or her behalf. Any such designation may include the authority to hear and determine any matter.

3) "Agreement" or "Contract" means the written agreement between HCA and the members of this Committee, including all exhibits, attachments, amendments and materials incorporated by reference.

4) "Centers for Medicare and Medicaid Services" or "CMS," means that division of the federal Department of Health and Human Services.

5) "CONTRACTOR" means the entity or person contracting with HCA to provide services pursuant to an Agreement as a member of the state of Washington Pharmacy and Therapeutics Committee.

6) "DUR" means the Drug Utilization Review Board established by the state of Washington Department of Social and Health Services, Medical Assistance Administration (DSHS/MAA), as set forth in WAC 388-530-1850 and the federal Social Security Act, Title 19 § 1927.

7) "Efficacy" means the potential effects of treatment by the drug under optimal circumstances (for example, patients all taking their doses at the right times, physicians prescribing correct doses, side effects appropriately monitored, etc). Efficacy studies are typically the foundation of new drug submissions to the FDA.

8) "Effectiveness" means the actual effects of treatment by the drug under "real life" conditions (for example, patients not always remembering to take their doses, physicians often not prescribing the FDA recommended doses, side effects not all controlled, etc).

9) "Evidence-based" means a process of independent and objective decision making based on consideration of objective data.

10) "OHSU EPC" means the Oregon Health & Science University, Evidence-Based Practice Center located in Portland, Oregon.

11) "Personal Information" includes, but is not limited to, information identifiable to an individual that relates to a natural person's health, finances, education, business, use or receipt of governmental services, or other activities, names, addresses, telephone

numbers, social security numbers, driver license numbers, financial profiles, credit card numbers, financial identifiers and other identifying numbers.

12) "Plan," means this Plan of Operation and Bylaws of the Committee.

13) "P&T Committee" or "Committee" means this independent Pharmacy and Therapeutics Committee established by the 2003 Legislature at Section 9, SB 6088, amending RCW 70.14.050(4). The P&T Committee also serves as the Drug Utilization Review Board (DUR) established by the state of Washington Department of Social and Health Services, Medical Assistance Administration (DSHSMAA), as set forth in WAC 388-530-1850 and the federal Social Security Act, Title 19 § 1927.

**D. OPERATING PRINCIPLES OF THE P&T COMMITTEE:**

The Committee is an independent technical review committee appointed by the Appointing Authority.

The objectives of this Committee shall be to:

1) Establish procedures to evaluate evidence-based reviews of prescription drug classes to assist in the formation of recommendations to the Appointing Authority regarding the development of a preferred drug list.

2) Consider and recommend action on independent evidence-based reviews of drug classes. Reviews of such drug classes shall be based on the evidence of safety, efficacy, and effectiveness available at the time of the review. The OHSU EPC, or another similar entity, will be contracted by the HCA to conduct the evidence-based reviews and make its findings available for detailed consideration by the Committee. All analysis, evidence and references brought to the Committee for review shall be the result of a rigorous assessment of the scientific evidence.

3) Evaluate the then-available evidence regarding the safety, efficacy, and effectiveness of the drug or drugs in a class of drugs based on the report provided by OHSU EPC or other contracted entity. Recommendations by the Committee to the Appointing Authority will be solely based on available evidence, not on cost considerations. The cost analysis will be performed by the Appointing Authority.

4) Identify the most clinically effective drug or drugs from among the drugs in the reviewed class or determine that there is sufficient evidence of similar safety, efficacy, and effectiveness for the drugs in a class to allow therapeutic interchange of the drugs within that class and forward its recommendation to the Appointing Authority for final deliberation and inclusion in the state's preferred drug list.

5) Serve as the Drug Utilization Review Board (DUR) established by the Washington state Department of Social and Health Services, Medical Assistance Administration (DSHSMAA), as set forth in W AC 388-530-1850 and the federal Social Security Act, Title 19 § 1927.

**E. PURPOSE OF THE P&T COMMITTEE:**

The purpose of the P&T Comm ittee is to evaluate available evidence regarding the relative safety, efficacy, and effectiveness of prescription drugs within a class or classes of prescription drugs and make recommendations to the Appointing Authority for its deliberation in the development of the state's preferred drug list established in Section 9, SB 6088 (as codified at RCW 70.14.050). In its evaluation, the P&T Committee m ay review and consider outcome studies of the long-term effects of drugs. The Committee shall also undertake DUR functions as required by DSHSM AA.

**F. PURPOSE OF THE PLAN OF OPERATION AND BYLAWS:**

It is the purpose of the Plan:

1) To establish a framework for the work of the Committee:
   a) To provide for selection of a chair, vice chair and such other officers as the Committee may determine;
   b) To create subcommittees or working groups as may be necessary;
   c) To establish regular times and places for meetings of the Committee;
   d) To conduct periodic evaluations to assure the general accuracy of data submitted to the Committee; and
   e) To review, consider and act upon any matters deemed by it to be necessary and proper to the administration of the Committee.

2) Establish procedures for consideration of evidence presented by OHSU EPC, or other comparable entity, for consideration and deliberation;

3) Adopt policies and procedures to evaluate the available evidence of safety, efficacy, and effectiveness of prescription drugs within a class to guide the development of a preferred drug list as required by RCW 70.14.050, for approval by the Appointing Authority; and

4) Establish a protocol for deciding when additional information or evidence is necessary for the work of the Committee and procedures for collection of additional information.

# Appendix IV. - Pharmacy & Therapeutics Committee Information

## G. REVIEW STANDARDS:

The P&T Committee will evaluate evidenced-based reviews of classes of prescription drugs provided by OHSU EPC or other contracted entity. The evidence-based reviews shall be based on well-designed, well-conducted studies that:

1) Consider the overall quality of the evidence available at the time of review, including a consideration of whether the study compares the safety, efficacy or effectiveness of similar drugs, rather than just compared to placebo;

2) Select and refine questions that assist the Committee in evaluating provider and patient perspectives;

3) Make use of an independent, systematic review of evidence of the relative safety, efficacy, and effectiveness of prescription drugs in a class;

4) Produce explicit, defensible recommendations based on careful evaluation of the available evidence at the time of the review;

5) Evaluate each class of drugs in a manner free of bias emphasizing the best evidence as reported by OHSU or other entity;

6) Review direct evidence, if available at the time of review, that addresses health outcomes rather than intermediate outcomes, including the spectrum of patients to whom a drug will be prescribed (not just highly selected patients in research studies); and

7) Consider the potential harms as well as the benefits of the intervention being considered.

The P&T Committee may consider such other evidence and reviews as the Committee appropriate to a well-informed review.

## H. REQUIREMENTS FOR MEMBERSHIP IN THE P&T COMMITTEE:

1) The Committee shall consist of no fewer than ten members appointed by the Appointing Authority. Each member serves at the pleasure of the Appointing Authority.

2) Members shall enter into an Agreement with the HCA at the time of their appointment to the Committee and shall act in accordance with all of its terms and conditions. Failure to do so may result in termination of the appointment.

# Appendix IV. - Pharmacy & Therapeutics Committee Information

3) The membership composition at all times shall be consistent with applicable federal requirements under the federal Social Security Act, Title 19 § 1927 and the requirements of DSHSMAA for its DUR. Therefore, pharmacists and physicians each shall represent at least 31% but no more than 51% of Committee membership respectively.

4) All members shall be actively practicing in their clinical area of expertise throughout the entire term of their appointments.

5) Members must have knowledge and expertise in one or more of the following:
   a) Clinically appropriate prescribing of covered outpatient drugs;
   b) Clinically appropriate dispensing and monitoring of covered outpatient drugs;
   c) Drug use review;
   d) Medical quality assurance;
   e) Disease state management; or
   f) Evidence-based medicine.

6) Members of the Committee shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any state agency administering state purchased health care programs during their term and for eighteen months prior to their appointment.

7) No member may have a substantial financial conflict of interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant monies. Members shall update their Conflict of Interest disclosure statements any time their circumstances change in order to ensure their information is current.

8) Any person appointed as a member of the Committee or any subcommittee, working group or advisory group established by the Committee, must disclose to the Appointing Authority any potential conflict of interest, including receipt of any remuneration, grants, or other compensation from a pharmaceutical manufacturer or pharmaceutical benefits management company prior to such appointment.

9) At each meeting any member of the Committee must recuse himself or herself from discussion and decision making of an entire drug class if he or she has a material conflict with any drug in that class. If any material conflict of interest is not disclosed by a member of the Committee on his or her application or prior to participation in consideration of an effected drug class or other action of the Committee, that person shall be subject to immediate dismissal.

# Appendix IV. - Pharmacy & Therapeutics Committee Information

10) Committee members shall not use the name of the Committee in any publication, meeting, negotiation, or promotion without prior approval of the Appointing Authority.

**I. APPOINTMENT PERIOD:**

1) Members shall be appointed to a term of three years and until a successor is duly appointed.

2) A member may be re-appointed to one additional three-year term for a total of six years. One year after the end of a six-year term, a person is eligible for appointment to one additional three-year term.

3) Committee members shall serve staggered three-year terms. Of the initial appointees, in order to provide for staggered terms, some members may be appointed initially for less than three years. If the initial appointment is for 24 or fewer months, that period of time shall not be counted toward the limitation of years of appointment described above.

4) Vacancies occurring on the Committee shall be filled by appointment of the Appointing Authority. If a vacancy occurs due to termination of a member during the term of his or her appointment, the initial appointment shall be for the remainder of the term of the vacant position. If the appointment is for 24 or fewer months, that period of time shall not be counted towards the limitation of years of appointment described above.

**J. COMPENSATION**

Members of the Committee will be compensated for participation in the work of the Committee in accordance with a personal services contract to be executed after appointment and prior to commencement of activities related to the work of the Committee.

**K. QUALIFICATIONS FOR APPOINTMENT:**

1) The Appointing Authority has the sole right to appoint Committee members and may terminate appointment of any member at any time during the term.

2) Appointment to the Committee shall be made by the Appointing Authority from a pool of interested applicants. Interested persons will be provided an opportunity to submit applications to the Appointing Authority. Members of the public may at any time recommend or nominate candidates for membership in the Committee.

# Appendix IV. - Pharmacy & Therapeutics Committee Information

3) As part of the application process, prospective Committee members shall complete a Conflict of Interest disclosure form, provided by the Appointing Authority, and after appointment, annually by July 1st of each year. Members must keep the disclosure statement current and provide updated information whenever circumstances change.

4) Members of the Committee may not participate in discussions or deliberations of any class of drugs or any agenda item for which a material conflict of interest is identified and may not vote on any such matter.

5) If a conflict of interest is so great as to make it difficult for a Committee member to participate meaningfully in the work of the P&T Committee, that person may be asked to resign. For example, resignation from the Committee may be requested if a member must recuse himself or herself from participation in more than one drug class review in a year.

6) Each Committee member must comply with all applicable local, state and federal licensing, certification, accreditation and registration standards and requirements necessary for the performance of this Agreement. He or she must remain in good standing with any applicable agencies, boards, professional licensing boards or commissions throughout the term of the Agreement.

**L. DUTIES OF P&T COMMITTEE MEMBERS:**

The duties of the Committee members include:

1) To establish procedures under which evidence-based reviews of classes of drugs are evaluated and considered.

2) To recommend to the Appointing Authority selected drugs from each class of drugs reviewed for the purpose of establishing a statewide preferred drug list.

3) To regularly attend meetings of the Committee. Failure of a member to regularly attend Committee meetings without adequate excuse shall be grounds for referral to the Appointing Authority for consideration of termination of membership in the Committee.

**M. OFFICERS:**

1) A Chair and a Vice Chair, selected by the members, shall manage the Committee and such other officers as are deemed necessary to administer the affairs of the Committee.

# Appendix IV. - Pharmacy & Therapeutics Committee Information

2) The term of office shall be for two years beginning on January 1st of the year following selection. Each officer shall hold office until a successor is duly elected.

3) The officers of the Committee shall fulfill the following functions:
   a) Chair: The chair shall be the principal executive officer of the Committee and shall generally supervise and control all of the business and affairs of the Committee. The Chair will be selected in even numbered years. The Chair may appoint such other officers, subcommittees, working groups or advisory groups, as he or she deems appropriate. The Chair shall:
      i) Preside at all meetings of the Committee;
      ii) Assist with the development and implementation of a program to publicize the existence of the Committee, qualifications for appointment and procedures for maintaining public awareness of the Committee;
      iii) Complete an annual report of the activities of the Committee by May 1st of each year and forward it to the Appointing Authority; and
      iv) Shall serve as an ex-officio member of all subcommittees, working groups or advisory groups.
   b) Vice Chair: The Vice Chair shall perform all duties of the Chair in the absence of the Chair or when the Chair is unable to act or refuses to act. When so acting, the Vice Chair shall have all of the powers and be subject to all of the restrictions of the Chair. The Vice Chair will be selected in odd numbered years. In addition, the Vice Chair shall:
      i) Perform such other duties as may be assigned by the chair or the Appointing Authority.
      ii) Act as the designee of the chair as ex-officio member of all Committees, working groups or advisory groups of the Committee.

4) Any officer selected or appointed by the Committee may be removed by a majority vote of the full Committee whenever in its judgment the best interests of the Committee would be served thereby.

5) The Chair and the Vice Chair should not be employed by the same entity. The Committee should strive to select officers from different regions of the state whenever possible.

6) For the 2003-4 year, the Chair shall be selected for a two-year term and the Vice Chair selected for a one-year term.

7) In the absence of both the Chair and the Vice Chair, an acting vice chair shall be appointed by a majority of the Committee present at that meeting and shall preside at that meeting of the Committee.

8) If a vacancy occurs in the office of Chair due to his or her death, resignation, removal, disqualification or other act of the Committee or the Appointing Authority, the Vice Chair shall automatically fill such vacancy until a successor is elected at the next regularly prescribed time. If a vacancy occurs in the office of Vice Chair, he or she shall be replaced by a majority vote of the members for the remainder of the term.

9) If contested, all elections of officers shall be conducted by secret ballot.

**N. VOTING AND QUORUM:**

1) All business of the Committee shall be transacted by motion or resolution, which may be made by any member in attendance, including the Chair or other person presiding at that meeting, and shall require a second. Voting on all motions and resolutions shall be by voice vote unless a member asks that the roll be called and that the vote of each member be recorded.

2) Each member of the Committee shall have one vote on each matter submitted to a vote of the Committee. The Chair shall be a voting member of the Committee.

3) The presence of six members (or one-half plus one if the membership is more than ten at the time of voting) shall constitute a quorum for the transaction of business.

4) A simple majority of those voting shall be required for all matters. A majority of the quorum must vote in favor for a motion in order for the motion to be adopted.

5) When a member must recuse himself or herself from acting on any matter, that person will not be counted for purposes of determining a quorum. Thus, if six members are present at a meeting where a vote is scheduled to occur and one member cannot participate, a quorum is not present and voting on the matter must be postponed or tabled or the matter fails for lack of a quorum, at the discretion of the Chair.

6) The acts of the majority of the Committee members present at a meeting at which a quorum is present shall be the acts of the Committee.

7) Members must be present to vote on each matter submitted to a vote of the members. A member will be considered to be present if he or she attends in person or by telephone conference call or any similar communication method.

# Appendix IV. - Pharmacy & Therapeutics Committee Information

## O. MEETINGS OF THE P&T COMMITTEE:

1) The P&T Committee shall meet at least quarterly and may meet at other times at the discretion of the Chair or the Appointing Authority.

2) Committee meetings shall in all respects comply with the provisions of the Open Public Meetings Act, chapter 42.30 RCW, and shall be subject to the provisions of the Administrative Procedure Act, chapter 34.05 RCW, as applicable.

3) The Committee shall constitute a technical review committee created to facilitate the development, acquisition, or implementation of state purchased health care under RCW 41.05.026, and as such may hold an Executive Session in accordance with Chapter 42.30 RCW during any regular or special meeting to discuss information submitted in accordance with RCW 41.05.026 (1) through (5).

4) Meetings shall be held at such time and place as the Chair or the Appointing Authority shall determine in order to conduct all business deemed necessary for the administration of the Committee.

5) At each meeting, the Committee shall review the status of all business before the Committee, review and act upon outstanding issues.

6) Advance notice of all meetings, both regular and special, of the Committee will be published in the *Washington State Register* and will be provided to interested parties. Persons interested in receiving information about meetings shall be encouraged to provide electronic addresses or information regarding such other means of receiving notice as may be determined to be appropriate by the Appointing Authority or the Chair.

7) Notice of the time and manner of any meeting may be given orally, or by telephone to the office, residence or normal place of business of each Committee member at least two days prior to the time of such meeting and such notice shall be sufficient for all purposes.

8) A recording of each meeting shall be made. The HCA staff person assigned to provide assistance to the Committee shall retain the original copy. Minutes of the Committee's deliberations may be, but need not be, kept and published. Minutes of the DUR will be kept and published by DSHSMAA staff.

9) A member of the Committee or a member of the public may request a transcription of the recording of a meeting. If a member of the public requests a transcription, the requesting party may be required by the Appointing Authority to pay for its

production. After completion, any transcription so made shall be made available to any person upon request.

10) Meetings of the Committee may be held by means of a conference telephone or similar communication equipment, by which all persons participating in the meeting can hear each other at the same time, and participation by such means shall constitute the presence of a person at a meeting.

**P. CONFLICTS OF INTEREST:**

1) Applicants may not have been employed by a Pharmaceutical Manufacturer or Pharmacy Benefit Manager at the time of application or within the most recent eighteen months.

2) The Initial Appointees shall complete a Conflict of Interest (COI) disclosure form shall be completed as part of the appointment process.

3) At any meeting of the Committee, members of the Committee must recuse themselves from discussion and decision making of an entire drug class if the member believes that a material conflict exists as to any drug in that class.

4) If any material conflict of interest is not disclosed by a member of the Committee on his or her application or prior to participation in consideration of an affected drug class or other action of the Committee, that person shall be subject to immediate dismissal.

5) If the conflicts of interest of any member are so great as to make participation in the work of the Committee ineffective, the member will be expected to resign or will be asked to resign.

6) Future applicants must submit a completed COI disclosure form with their application before the Appointing Authority considers their appointments. All disclosed conflicts will be considered before an offer of appointment is made.

**Q. STAFF ASSISTANCE:**

1) Staff assistance to the Committee will be provided by HCA employees, independent contractors employed by the HCA for this purpose, or such other supporting staff as the Appointing Authority may deem appropriate or necessary to assure that the mission of the Committee is carried out.

2) Staff assistants shall cause all votes of all proceedings to be recorded and shall cause a recording of the meeting to be made and transcribe the recordings, upon request.

3) Staff shall:
   a) Give or cause to be given, notice of all meetings, including publication in the *Washington State Register*, to all members of the Committee and such parties who have advised staff of their interest in the activities and meetings of the Committee;
   b) Act as custodian of the records of the Committee;
   c) Keep a register of the address of each member, maintain a record of the names of members entitled to vote, and provide public access to all such records;
   d) Assist Committee members to complete reports of expenses, as may be required for reimbursement by the state and keep accurate accounts of such reports; and
   e) Perform such other duties as may be prescribed by the Committee, the Appointing Authority, or the HCA Administrator.

**R. EXPENSES OF COMMITTEE MEMBERS:**

The expenses for which members of the Committee will be reimbursed are in accordance with the personal services contracts that shall be executed prior to the member's first meeting.

**S. CONTRACTS:**

1) The Committee has no power to enter into contracts, but may recommend that the HCA enter into such contracts as are necessary or proper to carry out the provisions and purposes of the Act or the work of the Committee. Such contract may include engagements of independent legal, actuarial, clinical, research or other consultants.

2) The Committee may suggest necessary or desirable corrections, improvements or additions to any such contract.

**T. SUBCOMMITTEES, WORKING GROUPS AND ADVISORY GROUPS:**

1) The Chair or the Appointing Authority may designate and appoint one or more subcommittees, working groups or advisory groups (collectively hereinafter "group").

2) Two or more Committee members shall serve on each such group.

3) Such other persons as may be designated by the Chair or the Appointing Authority may serve on any group.

4) No group shall have authority to amend, alter, or repeal this Plan, adopt any action contrary to the Committee, or remove any member or take any action on behalf of the Committee or the state of Washington.

5) The designation and appointment of any group and the delegation thereto of any authority of the Committee, shall not operate to relieve the Committee, or officers of the Committee, or any member of the Committee of any responsibility imposed upon him or her by law, rule or this Plan.

6) Any member of any group may be removed by the Chair or the Appointing Authority whenever the best interests of the Committee or the state will be best served by such removal.

**U. COUNSEL TO THE COMMITTEE:**

The Assistant Attorney General providing general legal advice to the HCA will provide general legal assistance to the Committee.

**V. INDEMNIFICATION**:

A Committee member may request defense and indemnification from the state for claims or actions arising out of performing, or in good faith purporting to perform, official duties of the Committee. Defense and indemnification will be provided to the extent permitted by applicable laws, including but not limited to RCW 4.92.060, .070 and .075.

**W. REPORTING**:

The Chair shall cause an annual report to be completed and presented to the Appointing Authority no later than May 1st of each year. The annual report shall include an account of the prior years activities.

**X. AMENDMENTS:**

1) This Plan may be altered, amended or repealed in whole or in part at any meeting of the Committee. Alterations, amendments or motions to repeal shall not be voted on at the meeting during which they are proposed.

2) At least ten days prior notice of the intent to alter, amend or repeal any portion of the Plan shall be given to the members for their consideration.

3) Alterations, amendments or motions to repeal any provision of the Plan shall require approval by a simple majority vote of a quorum of the Committee.

4) All alterations, amendments, or motions to repeal all or a part of this Plan are subject to review and approval by the Appointing Authority before becoming effective.

5) Any amendments or alterations to this Plan must comply with the Act and other applicable State and federal laws.

**Y. TERMINATION:**

The Committee shall continue in existence subject to termination in accordance with requirements of laws of the state of Washington or action of the Appointing Authority. In case of termination, to the extent consistent with such laws or consistent with the action of the Appointing Authority, the Committee shall continue operating only to the extent necessary to orderly complete the work of the Committee.

**Z. EFFECTIVE DATE:**

This Plan shall be effective the date of adoption by the Committee and approval by the Appointing Authority, and shall terminate at termination of the Committee.

This Plan of Operation and Bylaws of the P&T Committee was duly adopted at the meeting of the P&T Committee on the _ day of , .

Signed:

_ Dan Lessler /S/ 12/17/2003 _
Chair

This Plan of Operation and Bylaws of the P&T Committee was approved by the Appointing Authority on the _ day of , .

By:

_ Pete Cutler /S/ 01/13/2004 _
Pete Cutler, Acting Administrator HCA, on behalf of the Appointing Authority

# Appendix V.

# Senate Bill 6088
# Laws and Rules
# For the Prescription Drug Program

# Appendix V. - Senate Bill 6088 Laws and Rules For the Prescription Drug Program

**CERTIFICATION OF ENROLLMENT**

**SENATE BILL 6088**

58th Legislature
2003 1st Special Session
Passed by the Senate June 5, 2003
YEAS 43 NAYS 5

President of the Senate

Passed by the House June 5, 2003
YEAS 95 NAYS 2

Speaker of the House of Representatives

CERTIFICATE

I, Milton H. Doumit, Jr., Secretary of the Senate of the State of Washington, do hereby certify that the attached is SENATE BILL 6088 as passed by the Senate and the House of Representatives on the dates hereon set forth.

Secretary

Approved

Governor of the State of Washington

FILED

# Appendix V. - Senate Bill 6088 Laws and Rules For the Prescription Drug Program

**Secretary of State**
**State of Washington**

---

## SENATE BILL 6088

---

Passed Legislature - 2003 1st Special Session

State of Washington 58th Legislature 2003 1st Special Session

By Senators Deccio, Thibaudeau, Winsley, Swecker and Franklin

Read first time . Referred to .

AN ACT Relating to making prescription drugs more affordable to seniors, the disabled, and state health care programs; amending RCW 69.41.150 and 70.14.050; adding new sections to chapter 74.09 RCW; adding new sections to chapter 41.05 RCW; adding a new section to chapter 69.41 RCW; adding new sections to chapter 43.131 RCW; creating new sections; prescribing penalties; and declaring an emergency.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

{+ NEW SECTION. +} Sec. 1. The legislature finds that prescription drugs are an effective and important part of efforts to maintain and improve the health of Washington state residents. However, their increased cost and utilization is straining the resources of many state health care programs, and is particularly hard on low-income elderly people who lack insurance coverage for such drugs. Furthermore, inappropriate use of prescription drugs can result in unnecessary expenditures and lead to serious health consequences. It is therefore the intent of the legislature to support the establishment by the state of an evidence-based prescription drug program that identifies preferred drugs, develop programs to provide prescription drugs at an affordable price to those in need, and increase public awareness regarding their safe and cost-effective use.

{+ NEW SECTION. +} Sec. 2. A new section is added to chapter 74.09 RCW to read as follows:

(1) To the extent funds are appropriated specifically for this purpose, and subject to any conditions placed on appropriations made for this purpose, the department shall design a medicaid prescription drug assistance program.
Neither the benefits of, nor eligibility for, the program is considered to be an entitlement.

(2) The department shall request any federal waiver necessary to implement this program. Consistent with federal waiver conditions, the department may charge enrollment fees, premiums, or point-of-service cost-sharing to program enrollees.

(3) Eligibility for this program is limited to persons:

(a) Who are eligible for medicare or age sixty-five and older;

(b) Whose family income does not exceed two hundred percent of the federal poverty level as adjusted for family size and determined annually by the federal department of health and human services;

(c) Who lack insurance that provides prescription drug coverage; and

(d) Who are not otherwise eligible under Title XIX of the federal social security act.

(4) The department shall use a cost-effective prescription drug benefit design. Consistent with federal waiver conditions, this benefit design may be different than the benefit design offered under the medical assistance program. The benefit design may include a deductible benefit that provides coverage when enrollees incur higher prescription drug costs as defined by the department. The department also may offer more than one benefit design.

(5) The department shall limit enrollment of persons who qualify for the program so as to prevent an overexpenditure of appropriations for this program or to assure necessary compliance with federal waiver budget neutrality requirements. The department may not reduce existing medical assistance program eligibility or benefits to assure compliance with federal waiver budget neutrality requirements.

(6) Premiums paid by medicaid enrollees not in the medicaid prescription drug assistance program may not be used to finance the medicaid prescription drug assistance program.

(7) This program will be terminated within twelve months after implementation of a prescription drug benefit under Title XVIII of the federal social security act.

(8) The department shall provide recommendations to the appropriate committees of the senate and house of representatives by November 15, 2003, on financing options available to support the medicaid prescription drug assistance program. In recommending financing options, the department shall explore every opportunity to maximize federal funding to support the program.

{+ NEW SECTION. +} Sec. 3. A new section is added to chapter 41.05 RCW to read as follows:

(1) In negotiating price discounts with prescription drug manufacturers for state purchased health care programs, the health care authority shall also negotiate such discounts for any Washington resident:

(a) Whose family income does not exceed three hundred percent of the federal poverty level as adjusted for family size and determined annually by the federal department of health and human services;

(b) Whose existing prescription drug need is not covered by insurance; and

(c) Who is: (i) At least fifty years old; or (ii) between the ages of nineteen and forty-nine and is otherwise eligible for benefits under Title II of the social security act, federal old age, survivors, and disability insurance benefits.

(2)(a) An attestation, which shall be submitted to the administrator, from an individual that the individual's family income does not exceed three hundred percent of the federal poverty level is sufficient to satisfy the eligibility requirement of subsection (1)(a) of this section.

(b) Any person willfully making a false statement in order to qualify for discounts under this section is guilty of a misdemeanor. Notice of such shall be included on the program enrollment form.

(3) The administrator shall charge participants in this program an annual enrollment fee sufficient to offset the cost of program administration.

(4) Any rebate or discount provided by a pharmaceutical manufacturer and made available to individuals under this section shall not be at the expense of retail pharmacies. This does not prohibit participating state agencies from using discounted pharmacy reimbursements for services or ingredients provided by the pharmacies.

{+ NEW SECTION. +} Sec. 4. A new section is added to chapter 41.05 RCW to read as follows:

The consolidated prescription drug purchasing account is created in the custody of the state treasurer. All fees collected under section 3(3) of this act shall be deposited into the account. Expenditures from the account may be used only for the purposes of section 3 of this act. Only the administrator or the administrator's designee may authorize expenditures from the account. The account is subject to allotment procedures under chapter 43.88 RCW, but an appropriation is not required for expenditures.

{+ NEW SECTION. +} Sec. 5. A new section is added to chapter 69.41 RCW to read as follows:

(1) Any pharmacist filling a prescription under a state purchased health care program as defined in RCW 41.05.011(2) shall substitute, where identified, a preferred drug for any nonpreferred drug in a given therapeutic class, unless the endorsing practitioner has indicated on the prescription that the nonpreferred drug must be dispensed as written, or the prescription is for a refill of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug, in which case the pharmacist shall dispense the prescribed nonpreferred drug.

(2) When a substitution is made under subsection (1) of this section, the dispensing pharmacist shall notify the prescribing practitioner of the specific drug and dose dispensed.

Sec. 6. RCW 69.41.150 and 1979 c 110 s 5 are each amended to read as follows:

(1) A practitioner who authorizes a prescribed drug shall not be liable for any side effects or adverse reactions caused by the manner or method by which a substituted drug product is selected or dispensed.

(2) A pharmacist who substitutes an equivalent drug product pursuant to RCW 69.41.100 through 69.41.180 as now or hereafter amended assumes no greater liability for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its established name.

# Appendix V. - Senate Bill 6088 Laws and Rules For the Prescription Drug Program

{+ (3) A pharmacist who substitutes a preferred drug for a nonpreferred drug pursuant to section 5 of this act assumes no greater liability for substituting the preferred drug than would be incurred in filling a prescription for the preferred drug when prescribed by name. +}

{+ NEW SECTION. +} Sec. 7. A new section is added to chapter 41.05 RCW to read as follows:

(1) The administrator shall establish and advertise a pharmacy connection program through which health care providers and members of the public can obtain information about manufacturer-sponsored prescription drug assistance programs. The administrator shall ensure that the program has staff available who can assist persons in procuring free or discounted medications from manufacturer-sponsored prescription drug assistance programs by:

(a) Determining whether an assistance program is offered for the needed drug or drugs;

(b) Evaluating the likelihood of a person obtaining drugs from an assistance program under the guidelines formulated;

(c) Assisting persons with the application and enrollment in an assistance program;

(d) Coordinating and assisting physicians and others authorized to prescribe medications with communications, including applications, made on behalf of a person to a participating manufacturer to obtain approval of the person in an assistance program; and

(e) Working with participating manufacturers to simplify the system whereby eligible persons access drug assistance programs, including development of a single application form and uniform enrollment process.

(2) Notice regarding the pharmacy connection program shall initially target senior citizens, but the program shall be available to anyone, and shall include a toll-free telephone number, available during regular business hours, that may be used to obtain information.

(3) The administrator may apply for and accept grants or gifts and may enter into interagency agreements or contracts with other state agencies or private organizations to assist with the implementation of this program including, but not limited to, contracts, gifts, or grants from pharmaceutical manufacturers to assist with the direct costs of the program.

(4) The administrator shall notify pharmaceutical companies doing business in Washington of the pharmacy connection program. Any pharmaceutical company that does business in this state and that offers a pharmaceutical assistance program shall notify the administrator of the existence of the program, the drugs covered by the program, and all information necessary to apply for assistance under the program.

(5) For purposes of this section, "manufacturer-sponsored prescription drug assistance program" means a program offered by a pharmaceutical company through which the company provides a drug or drugs to eligible persons at no charge or at a reduced cost. The term does not include the provision of a drug as part of a clinical trial.

{+ NEW SECTION. +} Sec. 8. A new section is added to chapter 74.09 RCW to read as follows:

Each of the state's area agencies on aging shall implement a program intended to inform and train persons sixty-five years of age and older in the safe and appropriate use of prescription and

nonprescription medications. To further this purpose, the department shall award development grants averaging up to twenty-five thousand dollars to each of the agencies upon a showing that:

(1) The agency has the ability to effectively administer such a program, including an understanding of the relevant issues and appropriate outreach and follow-up;

(2) The agency can bring resources to the program in addition to those funded by the grant; and

(3) The program will be a collaborative effort between the agency and other health care programs and providers in the location to be served, including doctors, pharmacists, and long-term care providers.

Sec. 9. RCW 70.14.050 and 1986 c 303 s 10 are each amended to read as follows:

(1) Each agency (({- listed in RCW 70.14.010 -})) {+ administering a state purchased health care program as defined in RCW 41.05.011(2) +} shall (({- individually or -})){+ , +} in cooperation with other agencies{+ , +} take any necessary actions to control costs without reducing the quality of care when reimbursing for or purchasing drugs. To accomplish this purpose, (({- each agency shall investigate the feasibility of and -})) {+ participating agencies +} may establish (({- a -})) {+ an evidence-based prescription +} drug (({- formulary designating which drugs may be paid for through their health care programs. For purposes of this section, a drug formulary means a list of drugs, either inclusive or exclusive, that defines which drugs are eligible for reimbursement by the agency -})) {+ program +}.

(2) In developing the {+ evidence-based prescription +} drug (({- formulary -})) {+ program +} authorized by this section, agencies:

(a) Shall prohibit reimbursement for drugs that are determined to be ineffective by the United States food and drug administration;

(b) Shall adopt rules in order to ensure that less expensive generic drugs will be substituted for brand name drugs in those instances where the quality of care is not diminished;

(c) Where possible, may authorize reimbursement for drugs only in economical quantities;

(d) May limit the prices paid for drugs by such means as {+ negotiated discounts from pharmaceutical manufacturers, +} central purchasing, volume contracting, or setting maximum prices to be paid;

(e) Shall consider the approval of drugs with lower abuse potential in substitution for drugs with significant abuse potential; (({- and -}))

(f) May take other necessary measures to control costs of drugs without reducing the quality of care {+ ; and

(g) Shall adopt rules governing practitioner endorsement and use of any list developed as part of the program authorized by this section +}.

(3) Agencies (({- may -})) {+ shall +} provide for reasonable exceptions{+ , consistent with section 5 of this act, +} to (({- the drug formulary required -})) {+ any list developed as part of the program authorized +} by this section.

(4) Agencies (({- may -})) {+ shall +} establish (({- medical advisory committees, or utilize committees already established, to assist -})) {+ an independent pharmacy and therapeutics

committee to evaluate the effectiveness of prescription drugs +} in the development of the (({- drug formulary required -})) {+ program authorized +} by this section.

{+ NEW SECTION. +} Sec. 10. A new section is added to chapter 41.05 RCW to read as follows:

The authority may adopt rules to implement this act.

{+ NEW SECTION. +} Sec. 11. By January 1, 2005, the administrator of the health care authority and the secretary of the department of social and health services shall submit to the governor and the legislature a progress report regarding the implementation of the programs created in this act.

{+ NEW SECTION. +} Sec. 12. A new section is added to chapter 43.131 RCW to read as follows:

The discount program under section 3 of this act shall be terminated June 30, 2010, as provided in section 13 of this act.

{+ NEW SECTION. +} Sec. 13. A new section is added to chapter 43.131 RCW to read as follows:

Section 3 of this act, as now existing or hereafter amended, is repealed effective June 30, 2011.

{+ NEW SECTION. +} Sec. 14. If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

{+ NEW SECTION. +} Sec. 15. If any part of this act is found to be in conflict with federal requirements that are a prescribed condition to the allocation of federal funds to the state, the conflicting part of this act is inoperative solely to the extent of the conflict and with respect to the agencies directly affected, and this finding does not affect the operation of the remainder of this act in its application to the agencies concerned.

Rules adopted under this act must meet federal requirements that are a necessary condition to the receipt of federal funds by the state.

{+ NEW SECTION. +} Sec. 16. This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and takes effect immediately.

--- END ---

# Appendix V. - Senate Bill 6088 Laws and Rules For the Prescription Drug Program

## Chapter 182-50 WAC

## PRESCRIPTION DRUG PROGRAMS

NEW SECTION

**WAC 182-50-001 Authority and purpose.** RCW 41.05.021 (1)(a)(iii) and 70.14.050 authorize the administrator to establish an independent Washington state pharmacy and therapeutics committee within the health care authority to evaluate available evidence of the relative safety, efficacy and the effectiveness of prescription drugs within a class of prescription drugs, in the development of an evidence-based prescription drug program for participating state purchased health care programs. This section requires the administrator to adopt rules governing practitioner endorsement and use of any preferred drug list developed as part of the prescription drug program.

NEW SECTION

**WAC 182-50-005 Definitions.** When used in this chapter:

(1) "Appointing authority" shall mean the following persons acting jointly: The administrator of the health care authority, the secretary of the department of social and health services, and the director of the department of labor and industries.

(2) "Committee" means the independent Washington state pharmacy and therapeutics committee created by RCW 41.05.021 (1)(a)(iii) and 70.14.050. At the election of the department of social and health services, the committee may serve as the drug use review board provided for in WAC 388-530-1850.

(3) "Drug" means the term as it is defined in RCW 69.41.010 (9) and (12).

(4) "Endorsing practitioner" means a practitioner who has reviewed the preferred drug list and has notified the health care authority that he or she has agreed to allow therapeutic interchange of a preferred drug for any nonpreferred drug in a given therapeutic class.

(5) "Practitioner" means a health care provider, except a veterinarian, as defined at RCW 18.64.011(9).

(6) "Preferred drug" means a drug selected by the appointing authority for inclusion in the preferred drug list used by applicable state agencies for state purchased health care programs.

(7) "Preferred drug list" or "PDL" means the list of drugs selected by the appointing authority to be used by applicable state agencies as the basis for the purchase of drugs in state purchased health care programs.

(8) "Prescription" has the meaning set forth in RCW 18.64.011(8).

(9) "Refill" means the continuation of therapy with the same drug (including the renewal of a previous prescription or adjustments in dosage) when a prescription is for an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug.

(10) "State purchased health care" has the meaning set forth in RCW 41.05.011(2).

(11) "Therapeutic alternatives" are drug products of different chemical structure within the same pharmacologic or therapeutic class and that are expected to have similar therapeutic effects and safety profiles when administered in therapeutically equivalent doses.

(12) "Therapeutic interchange" means to dispense, with the endorsing practitioner's authorization, a therapeutic alternative to the prescribed drug.

NEW SECTION

**WAC 182-50-010 Purpose of the pharmacy and therapeutics committee.** The purpose of the committee is to evaluate the available evidence of the relative safety, efficacy, and effectiveness of prescription drugs within a class of prescription drugs and make recommendations to the appointing authority for its deliberation in the development of the preferred drug list established in RCW 70.14.050.

NEW SECTION

**WAC 182-50-015 Open Public Meetings Act and Administrative Procedure Act; exception as technical review committee.** (1) Meetings of the pharmacy and therapeutics committee shall in all respects comply with the provisions of the Open Public Meetings Act, chapter 42.30 RCW, and shall be subject to the provisions of the Administrative Procedure Act, chapter 34.05 RCW, as applicable.

(2) The pharmacy and therapeutics committee shall constitute a technical review committee created to facilitate the development, acquisition, or implementation of a preferred drug list, for the purposes of state purchased health care under RCW 41.05.026, and as such may hold an executive session in accordance with chapter 42.30 RCW during any regular or special meeting to discuss information submitted in accordance with RCW 41.05.026 (1) through (5).

NEW SECTION

**WAC 182-50-025 Membership and qualifications of pharmacy and therapeutics committee.** (1) The committee shall consist of no fewer than ten members appointed by the appointing authority.

(2) The appointing authority has the sole right to appoint committee members and may terminate appointment of any member at any time during the term.

(3) The appointing authority will make appointments to the committee from a pool of interested applicants. Interested persons will be provided an opportunity to submit applications to the appointing authority.

(4) Members shall enter into an agreement with the health care authority at the time of their appointment to the committee and shall act in accordance with all of its terms and conditions. Failure to do so may result in termination of the appointment.

(5) The membership composition at all times shall be consistent with applicable federal requirements under the Federal Social Security Act, Title 19 § 1927 and the requirements of the department of social and health services medical assistance administration for its drug utilization review board. Therefore, pharmacists and physicians each shall represent at least thirty-one percent, but no more than fifty-one percent of committee membership respectively.

(6) Members must be actively practicing in their clinical area of expertise throughout the entire term of their appointments.

(7) Members must have knowledge and expertise in one or more of the following:

(a) Clinically appropriate prescribing of covered outpatient drugs;

(b) Clinically appropriate dispensing and monitoring of covered outpatient drugs;

(c) Drug use review;

(d) Medical quality assurance;

(e) Disease state management; or

(f) Evidence-based medicine.

(8) Members of the committee shall not be employed by a pharmaceutical manufacturer, a pharmacy benefits management company, or by any state agency administering state purchased health care programs during their term shall not have been so employed and for eighteen months prior to their appointment.

(9) A member shall not have a substantial financial conflict of interest including any interest in any pharmaceutical company, including the holding of stock options or the receipt of honoraria or consultant moneys. The appointing authority in its sole discretion may disqualify any potential member if it determines that a substantial conflict of interest exists.

(10) As part of the application process, prospective committee members shall complete a conflict of interest disclosure form, provided by the appointing authority, and after appointment, annually by July 1st of each year. Members must keep their disclosure statements current and provide updated information whenever circumstances change.

(11) Committee members must agree to keep all proprietary information confidential.

NEW SECTION

**WAC 182-50-030 Period of appointment.** (1) Members shall be appointed to a term of three years and shall serve until a successor is duly appointed. A member may be reappointed to one additional three-year term for a total of six years. One year after the end of a six-year term, a person is eligible for appointment to one additional three-year term.

(2) Committee members serve staggered three-year terms. Of the initial appointees, in order to provide for staggered terms, some members may be appointed initially for less than three years. If the initial appointment is for less than twenty-four months, that period of time shall not be counted toward the limitation of years of appointment described in subsection (1) of this section.

(3) Vacancies on the committee will be filled for the balance of the unexpired term from nominee lists for the appropriate committee category as provided under WAC 182-50-025.

(4) Members of the committee will be compensated for participation in the work of the committee in accordance with a personal services contract executed after appointment and prior to commencement of activities related to the work of the committee.

NEW SECTION

**WAC 182-50-035 Duties.** Committee members shall:

(1) Select a chair and a vice-chair from among the committee membership.

(2) Meet at least quarterly and may meet at other times at the discretion of the chair.

(3) Adopt a plan of operation that sets forth the policies and procedures established by the committee to develop an evidence-based prescription drug program as authorized by state law for approval by the appointing authority.

(4) Operate according to the plan of operation as approved by the appointing authority.

NEW SECTION

**WAC 182-50-200 Endorsing practitioner therapeutic interchange program; effect of practitioner's endorsing status; dispense as written instructions.** (1) When filling prescriptions for participating state purchased health care programs, pharmacists shall dispense a preferred drug in place of a drug not included in the preferred drug list in a given therapeutic class whenever pharmacists receive a prescription from an endorsing practitioner except:

(a) If the endorsing practitioner determines the nonpreferred drug is medically necessary by indicating "dispense as written" on the prescription; or

(b) If the prescription is a refill of an antipsychotic, antidepressant, chemotherapy, antiretroviral, or immunosuppressive drug.

(2) When a therapeutic interchange is made, the pharmacist shall notify the endorsing practitioner of the specific drug and dose dispensed.

(3) When a nonendorsing practitioner issues a prescription for a drug not included in the preferred drug list, the pharmacist shall dispense the prescribed drug in accordance with the requirements of RCW 69.41.100 through 69.41.180.